LOWERING THE COST OF PRESCRIPTION DRUGS: REDUCING BARRIERS TO MARKET COMPETITION

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTEENTH CONGRESS

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C O N T E N T S

WITNESSES

SUBMITTED MATERIAL

LOWERING THE COST OF PRESCRIPTION DRUGS: REDUCING BARRIERS TO MARKET COMPETITION

WEDNESDAY, MARCH 13, 2019

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:02 a.m., in John D. Dingell Room 2123, Rayburn House Office Building, Hon. Anna G. Eshoo (chairwoman of the subcommittee) presiding.

Present: Representatives Eshoo, Butterfield, Matsui, Castor, Sarbanes, Luján, Schrader, Kennedy, Cárdenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragán, Blunt Rochester, Rush, Pallone (ex officio), Burgess (subcommittee ranking member) Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Carter, Gianforte, and Walden (ex officio).

Staff present: Jeffrey C. Carroll, Staff Director; Luis Dominguez, Health Fellow; Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Megan Howard, FDA Detailee; Zach Kahan, Outreach and Member Service Coordinator; Joe Orlando, Staff Assistant; Tim Robinson, Chief Counsel; Samantha Satchell, Professional Staff Member; Kimberlee Trzeciak, Senior Health Policy Advisor; C. J. Young, Press Secretary; Mike Bloomquist, Minority Staff Director; Adam Buckalew, Minority Director of Coalitions and Deputy Chief Counsel, Health; Jordan Davis, Minority Senior Advisor; Margaret Tucker Fogarty, Minority Staff Assistant; Theresa Gambo, Minority Human Resources/Office Administrator; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; James Paluskiewicz, Minority Chief Counsel, Health; Zack Roday, Minority Communications Director; Kristen Shatynski, Minority Professional Staff Member, Health; and Danielle Steele, Minority Counsel, Health.

Ms. ESHOO. Good morning, everyone. The Subcommittee on Health will now come to order.

The Chair now recognizes herself for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

First of all, welcome to all of our witnesses. It is a pleasure and an honor to have you here with us today, to everyone that is in the

hearing room, and to all of my colleagues. This is the first hearing of the Health Subcommittee on drug pricing—legislative hearing.

For too long, the American people have been subjected to the abuse of the patent system by pharmaceutical companies, and generic companies entering into agreements and employing tactics that block competition and keep prices high. When brand and generic manufacturers employ these tactics, it is really the American people that lose out by having to pay more for the prescription drugs because there is less competition.

We know that when generics come to market, they can drive prices down exponentially for consumers. The United States has the lowest, generic drug prices in the world. So where there are competition between brand drugs and multiple generics, it works. The bills we are considering today will inject competition in the system sooner, move drugs to the market more quickly, and lower costs. We are examining the CREATES Act, authored by Representatives Cicilline, Sensenbrenner, Nadler, Collins, Welch, McKinley, and the FAST Generics Act, authored by Representatives Welch, McKinley, and Cicilline, which address barriers to generic development.

Both bills take a different approach to address the stalling tactics brand manufacturers use to restrict access to samples of their products. Generic companies rely on samples of the brand product to ensure that the generic is identical to the brand drug, so that patients can use the products interchangeably.

The second group of bills addresses marketing abuse barriers. The BLOCKING Act, introduced by Representatives Schrader and Carter, target generics that have been granted exclusivity and then block other products from coming to market. This delaying of their exclusivity periods is referred to as parking, and I believe Secretary Azar yesterday referred to it as squatting.

When a company delays the start of the exclusivity period of a product, it not only delays other generics from coming to market, it also delays lower prices reaching patients sooner.

During our hearing on the fiscal year 2020 budget yesterday, Secretary Azar explained that this parking behavior leads to an average delay of 12 months for a generic to come to market. The Protecting Consumer Access to Generic Drugs Act, introduced by Representative Rush, and the FAIR Generic Drugs Act, introduced by Representative Barragán target pay-for-delay agreements. This is brand manufacturers paying generic companies to delay entering the market with generic versions of the drug.

Remember that saying, it takes two to tango, and they have tangoed. And both are wrong. The Protecting Consumer Access to Generic Drugs Act prohibits these pay-for-delay agreements outright. While the FAIR Generics Act sets up a different, legal framework that discourages brand manufacturers and generic companies from entering into these agreements.

The last group of bills make important updates to the Orange and Purple Books at the FDA by amending what information must be included and requiring these resources to be published in a user-friendly way. When manufacturers are considering where to invest their research and development dollars, they use the Orange

and Purple Books to determine what patents are currently active and which patents will be expiring soon.

Representative Kelly and myself introduced the Purple Book, and at any rate, this is a legislative hearing to discuss the bills, to close loopholes, eliminate bad practices in the drug system, all in order to bring the costs down.

Welcome to our witnesses and we look forward to your testimony.

[The prepared statement of Ms. Eshoo follows:]

PREPARED STATEMENT OF HON. ANNA G. ESHOO

Welcome to the first hearing of the Health Subcommittee on drug pricing.

For too long, the American people have been subjected to the abuse of the patent system by pharmaceutical companies and generic companies entering into agreements and employing tactics that block competition and keep prices high.

When brand and generic manufacturers employ these tactics, the American people lose out by having to pay more for their prescription drugs because there is less competition.

We know that when generics come to market, they can drive prices down exponentially for consumers.

The United States has the lowest generic drug prices in the world, so where there are competition between brand drugs and multiple generics, it works.

The bills we're considering today will inject competition in the system sooner, move drugs to the market more quickly, and lower costs.

We're examining the CREATES Act authored by Representatives Cicilline, Sensenbrenner, Nadler, Collins, Welch and McKinley, and the FAST Generics Act authored by Representatives Welch, McKinley, and Cicilline, address barriers to generic development. Both bills take a different approach to address the stalling tactics brand manufacturers use to restrict access to samples of their products.

Generic companies rely on samples of the brand product to ensure that the generic is identical to the brand drug so that patients can use the products interchangeably.

The second group of bills addresses marketing abuse barriers.

The BLOCKING ACT introduced by Representatives Schrader and Carter targets generics that have been granted exclusivity and then block other products from coming to market. This delaying of their exclusivity periods is referred to as "parking".

When a company delays the start of the exclusivity period of a product, it not only delays other generics from coming to market. It also delays lower prices reaching patients sooner.

During our hearing on the FY2020 Budget yesterday, Secretary Azar explained that this "parking" behavior leads to an average delay of 12 months for a generic to come to market.

The Protecting Consumer Access to Generic Drugs Act introduced by Representative Rush, and the FAIR Generic Drugs Act introduced by Representative Barragán, target pay-for-delay agreements. This is brand manufacturers paying generic companies to delay entering the market with generic versions of the drug. It takes two to tango and manufacturers and generic companies are both wrong.

The Protecting Consumer Access to Generic Drugs Act prohibits these Pay for Delay agreements outright, while the FAIR Generics Act sets up a different legal framework that discourages brand manufacturers and generic companies from entering into these agreements.

The last group of bills make important updates to the Orange and Purple Books at the FDA by amending what information must be included and requiring these resources to be published in a user-friendly way online.

When manufacturers are considering where to invest their research and development dollars, they use the Orange and Purple Books to determine what patents are currently active and which patents will be expiring soon.

The Orange Book Transparency Act was introduced by Representative Kelly, and I introduced the Purple Book Continuity Act.

This is a legislative hearing to debate bills that will close loopholes and eliminate bad practices in the drug system in order to bring down costs. I look forward to passing bills that will be considered in the full House.

Welcome to our witnesses and we look forward to your testimony.

Ms. ESHOO. I now would like to yield the remainder of my time to Representative Welch.

Mr. WELCH. Thank you very much. Thank you, first of all, Madam Chair, for your leadership on this incredible issue of drug pricing.

Second, we have got an opportunity, bipartisan, to finally tackle the rip-off pricing in the pharma system. And yesterday we had Secretary Azar here, who said that the administration supports efforts to end pay-for-delay, to have FAST and the CREATES Act passed to help us to ban product-hopping, to crack down on the citizen-petition abuses.

So we have an opportunity, bipartisan, to address something that has been an enormous burden on the American consumer and the American taxpayer. And thank you for your leadership, and I look forward to working with you and our ranking member to make progress. Thank you.

Ms. ESHOO. I thank the gentleman. I now have the pleasure of recognizing the ranking member of the subcommittee, Mr. Burgess, for 5 minutes for his opening statement.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Yes, just prior to doing that, if I could ask to be recognized for a unanimous-consent request for Representative Duncan to be able to participate in today's hearing.

Ms. ESHOO. So ordered.

Mr. BURGESS. And also if he is yielded time to make an opening statement, enter a written opening statement in the record, question witnesses during the hearing, and submit additional questions for the record at the end of the hearing.

Ms. ESHOO. So ordered.

Mr. BURGESS. So, thank you. We are having a hearing that will touch upon the important topic of drug pricing, and I will admit to being frustrated that we are not considering, perhaps, some additional policies. As the chairman of this subcommittee in December of 2017, I held a drug-supply-chain hearing with a total of ten witnesses. The number of witnesses pushed the limits of how many individuals we could actually fit at one table, and I do recall getting some criticism from the then ranking member of the full committee, but I thought it was critical that we had someone present—or someone to represent each level of the drug-supply chain.

Now, as evidenced at that hearing, there are a number of conflicting opinions held by the entities along the supply chain, but that does not mean that we should not listen to them. It is likely that legislation to address drug pricing will ruffle some feathers, and that is OK. However, it is not acceptable to intentionally legislate within a black box.

A few of the bills before us today are bipartisan and have been previously introduced, and there are numerous new pieces of legislation. The text of the bills was not shared with the Republicans until last Monday. And that, of course, does not comport with the two-week rule that has been considered sacred for years. Not a Republican rule. This was a rule that both Chairman Waxman and Chairman Dingell held in high regard.

I will reiterate what I said last week. Bipartisanship is asking for my input, not just my vote. There are some of these bills that we might have been able to work and collaborate, and we may still be able to collaborate going forward, but giving a Member less than 24 hours to sign on to a piece of legislation they have never seen is discourteous, especially when we have said at each step along the way, in this Congress, that we are willing to work in a bipartisan fashion. But if we don't have a seat at the table during the drafting process, you can expect it to take longer as we do our due diligence in vetting the policies.

Additionally, no stakeholders had been consulted in the drafting of these bills, including the Association for Accessible Medicines, the generics manufacturers whose bills—some of these bills are intended to benefit. In fact, the generics manufacturers have either not commented on, or opposed some of the bills that are before us this morning, and we may hear more about that later.

Several of these bills had not seen the light of day outside of the chairman's staff, the Members these bills were assigned to, and House legislative counsel. These bills have received no input from stakeholders, no technical assistance from the agencies, specifically the Food and Drug Administration, and the Federal Trade Commission.

As chairman of the subcommittee, I would have never thought about holding a hearing on seven bills that were not shared with the other party until 9 days before the hearing, not to mention, without the agency witnesses. It is unthinkable, that the Food and Drug Administration was not invited to testify at this hearing.

And these are not grab-bag, drug-pricing issues. These are seven pieces of complex legislation that all intricately involve the Food and Drug Administration, and not only was the Food and Drug Administration not invited to present us with their thoughts about these bills, but the Food and Drug Administration was not consulted for technical assistance on any of these bills prior to this hearing.

I learned that the staff spoke with the Food and Drug Administration about these bills for the first time yesterday, and the agency had more questions than answers. As the agency that would be largely tasked with implementing these bills, should they be signed into law, it is troubling that agency witnesses were not considered. Ideally, the Republicans could have called the FDA as a Republican witness, but we didn't get the notice for the hearing in time to allow us to do so. As you recall, is it does take some time to get testimony cleared through Office of Management of the Budget.

But I do want to thank the witnesses who are here today, and I want to thank them for agreeing to testify before us this morning. This is a complex problem, and as someone, I think, previously has said, there is no one single solution. So there is no 100 percent solution, but there are probably 101 percent solutions, and if we will get to work on some of them, we can achieve some benefit for the American people.

But I do again thank the witnesses, and I think we can utilize their expertise while we highlight the flaws in some of these bills, we can accentuate what is positive in some of these bills, and use

their input to improve upon the bills during the path forward. And I will yield back my time.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Thank you, Chairwoman Eshoo. Today, we are having a hearing that will touch upon the important topic of drug pricing; although I am frustrated that we are not considering more substantive policies. As the chairman of this subcommittee in December of 2017, I held a drug supply chain hearing with a total of ten witnesses. While the number of witnesses pushed the limits on how many individuals we could fit at one table, I thought it was critical that we have someone to represent each level of the drug supply chain.

As evidenced by that hearing, there are a number of conflicting opinions held by the entities along the supply chain, but that does not mean that we should not listen to them. It is likely that legislation to address drug pricing will ruffle some feathers, and that is OK; however, it is not acceptable to intentionally legislate in a black box.

While a few of the bills before us today are bipartisan and have been previously introduced, there are numerous new pieces of legislation. The text of these bills were not shared with the Republicans until last Monday, which violates the two week rule that has been considered sacred for years. This was not a Republican rule. This is a rule that both Chairman Waxman and Chairman Dingell held in high regard. I will reiterate what I said last week—bipartisanship is asking for my input, not just for my vote.

There are some of these bills that we might have been able to work together on, and may be able to partner on going forward. Giving a Member less than 24 hours to sign onto a piece of legislation they have never seen is discourteous, especially when we have said at each hearing thus far this Congress that we are willing to work in a bipartisan way. If we don't have a seat at the table during the drafting process, you can expect us to take longer to do our due diligence in vetting the policies.

Additionally, no stakeholders had been consulted in the drafting of these bills, including the Association for Accessible Medicines—the generics manufacturers, whom these bills are supposedly intended to benefit. In fact, the generics manufacturers have either not commented on, or oppose, a number of the bills before us this morning.

Several of these bills had not seen the light of day outside of Chairman Pallone's staff, the Members these bills were assigned to, and House legislative counsel. These bills have received no input from stakeholders, and no technical assistance from the agencies—namely the Food and Drug Administration and the Federal Trade Commission.

As Chairman of this Subcommittee, I never would have even thought about holding a hearing on seven bills that were not shared with nine days until the hearing, not to mention without the agency witnesses. It is unthinkable that the Food and Drug Administration was not invited to testify at this hearing.

This is not a grab-bag drug pricing hearing. These are seven pieces of complex legislation that all intricately involve the FDA. Not only was FDA not invited to present us with their thoughts about these bills, the FDA was not consulted for technical assistance on any of these bills prior to this hearing. I learned that staff spoke with FDA about these bills for the first time yesterday, and the agency had more questions than answers. As the agency that would largely be tasked with implementing these bills should any be signed into law, I find it immensely troubling that they agency witnesses were not considered by the Democrats. Ideally, we could have called FDA in to be our Republican witness, but we did not get notice that this hearing was happening with enough time to do so.

I do want to thank the witnesses that are here for agreeing to testify before us this morning. I do hope that we can use their expertise to highlight the flaws in some of these bills, and that we can utilize their input to improve upon some of the bills on which we may find a bipartisan path forward. I yield back.

Ms. ESHOO. I thank the gentleman.

I would just like to say a few things about—a few remarks. First of all, the sky is really not caving in. Half of the bills being considered have been introduced in previous congresses. They are not brand-new. And multiple are bipartisan. We shared language with

the minority on March 4th. We included the minority in all witness calls, we are open to having conversations on language. This is a legislative hearing. It is the first step, and to have the FDA—agencies don't come to legislative hearings to comment on the legislation.

So this is an important—I believe that this subcommittee is the first to be taking up, with a legislative hearing, seven bills, on drug pricing, and I don't believe any other committee in the House has done that, nor has it occurred in the Senate as yet. So on we go.

Now I would like to call on the—recognize the chairman of the full committee for his opening statement, 5 minutes. Mr. Pallone?

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Madam Chair. And let me also add, from a process point of view, you know, the Energy and Commerce Committee is one of the few—maybe the only one—that has complete, regular order. Meaning that, you know, we have hearings in the subcommittee; we have markups in the subcommittee; we then have a markup in the full committee. And this has been done on a bipartisan basis.

So I just—I just want to remind everyone that when you talk about process, you know, we really follow regular order, and I am not trying to disapprove of other committees, but there are very few committees that actually do that entire process.

But in any case, today the committee begins the process of fulfilling our commitment to provide some much-needed relief to Americans struggling to pay for skyrocketing prescription drugs. I am pleased that we will be examining policies that will help to bring the high cost of prescription drugs down. The American people have justifiably been demanding congressional action to make prescription drugs more affordable, and who can blame them.

Prices are so high that recent data shows that nearly a quarter of Americans didn't fill a prescription in the past year due to the high cost. Nineteen percent say they skipped a dose or cut pills in half because they wanted to make them last longer. These are choices Americans simply should not have to make. It is unacceptable and could, in fact, lead to greater illness and higher medical costs down the road.

And it is time for Congress to help make prescription drugs more affordable. One way to achieve this goal is to facilitate greater competition from generic and biosimilar manufacturers. And I believe reducing barriers to generic drugs and increasing competition in the pharmaceutical market will benefit American families who are struggling to afford their medications.

And let me stress that—competition. You know, a lot of times Congress is accused of, you know, trying to do things that are not competitive. This is clearly the opposite. This is competition. This is market-driven. This is capitalism. That is what we are about here.

Generic drugs play a critical role in increasing access and reducing costs in our healthcare system. In 2017, the entry of generic drugs to the market saved patients and the public $265 billion, in-

cluding over $82 billion for Medicare alone, and that is more than $1,900 per enrollee. These numbers alone demonstrate the substantial cost savings to consumers when we ensure generic products can come to market as soon as possible.

The proposals before us today will close loopholes that some drug companies are exploiting to game the system, unfairly raise drug prices, and take advantage of American families. And more specifically, the bills address three key barriers for generics—patent listing, drug development and market entry, and market barriers. Two of the bills we'll be discussing, the Orange Book Transparency Act of 2019, introduced by Representative Kelly, and the Purple Book Care Continuity Act of 2019, introduced by Chairwoman Eshoo, would help to increase accuracy and transparency of the two databases that guide development decisions for generic and biosimilar manufacturers. These bills would help generics overcome the barrier of patent listing.

Two other bills—the CREATES Act and the FAST Generics Act—led here on the committee by Representatives Welch and McKinley, would help address the barrier of drug development and market entry. Today the use of restrictive distribution systems, including REMS by certain manufacturers, delays access to samples of branded drug products for development purposes. It also impedes market entry through delays in negotiations on single shared system REMS. And this important legislation would eliminate these barriers.

And, finally, we are considering three policies focused on market barriers—again, market, I stress market—the BLOCKING Act, introduced by Representatives Schrader and Carter, would address delays that occur when first-time generics are unable to be approved. This blocks the approval of other generics.

The Protecting Consumer Access to Generic Drugs Act of 2019, introduced by Representative Rush, would discourage use of pay-for-delay agreements that result in generics delaying development or market entry.

And, finally, the FAIR Generics Act, introduced by Representative Barragán, would strengthen incentives for generic first applicants to enter the market on the earliest possible date and disincentive patent settlement agreements that delay generic entry.

These are all commonsense solutions that will remove unnecessary barriers to competition, and again I stress competition. These bills are a strong first step in making prescription drugs more affordable and providing real relief to hardworking Americans that are being price-gouged at the pharmacy counter.

Now, I know there are some people that think that, you know, generics aren't a major factor in bringing drug prices down. Totally disagree. My predecessors—Congressman Dingell, Congressman Waxman—very much believed that generics will lower prices and that generic competition is important, and I strongly believe that as well. And that is why we want to bring back the generics as even more a factor in bringing drug prices down, because we believe very strongly in that.

So thank you, Madam Chair. This is a very important hearing.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Today this committee begins the process of fulfilling our commitment to provide some much-needed relief to Americans struggling to pay for skyrocketing prescription drugs.

I am pleased that we will be examining policies that will help to bring the high costs of prescription drugs down.

The American people have justifiably been demanding Congressional action to make prescription drugs more affordable, and who can blame them. Prices are so high that recent data shows that nearly a quarter of Americans didn't fill a prescription in the past year due to the high cost. Nineteen percent say they skipped a dose or cut pills in half because they wanted to make them last longer. These are choices Americans simply should not have to make. It is unacceptable and could in fact lead to greater illness and higher medical costs down the road.

It is time for Congress to help make prescription drugs more affordable. One way to achieve this goal is to facilitate greater competition from generic and biosimilar manufacturers. I believe reducing barriers to generic drugs and increasing competition in the pharmaceutical market will benefit American families who are struggling to afford their medications.

Generic drugs play a critical role in increasing access and reducing costs in our healthcare system. In 2017, the entry of generic drugs to the market saved patients and the public $265 billion, including over $82 billion for Medicare alone—that's more than $1,900 per enrollee. These numbers alone demonstrate the substantial cost savings for consumers when we ensure generic products can come to market as soon as possible.

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More specifically, the bills address three key barriers for generics—patent listing, drug development and market entry, and market barriers.

Two of the bills we will be discussing—the Orange Book Transparency Act of 2019 introduced by Rep. Kelly, and the Purple Book Continuity Act of 2019 introduced by Chairwoman Eshoo—would help to increase accuracy and transparency of the two databases that guide development decisions for generic and biosimilar manufacturers. These bills would help generics overcome the barrier of patent listing.

Two other bills, the CREATES Act and the FAST Generics Act, led here on the Committee by Reps. Welch and McKinley, would help address the barrier of drug development and market entry. Today, the use of restricted distribution systems, including REMS, by certain manufacturers delays access to samples of branded drug products for development purposes. It also impedes market entry through delays in negotiations on single-shared system REMS. This important legislation would eliminate these barriers.

And finally, we are considering three policies focused on market barriers. The BLOCKING Act, introduced by Reps. Schrader and Carter, would address delays that occur when first time generics are unable to be approved. This blocks the approval of other generics. The Protecting Consumer Access to Generic Drugs Act of 2019, introduced by Rep. Rush, would discourage the use of pay-for-delay agreements that result in generics delaying development or market entry. And finally, the FAIR Generics Act, introduced by Rep. Barragán, which would strengthen incentives for generic first applicants to enter the market on the earliest possible date and disincentive patent settlement agreements that delay generic entry.

These are all commonsense solutions that will remove unnecessary barriers to competition. These bills are a strong first step in making prescription drugs more affordable and providing real relief to hardworking Americans that are being price gouged at the pharmacy counter.

Ms. ESHOO. We thank the chairman, and now it is my pleasure to recognize the ranking member of the full committee, Mr. Walden.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Well, good morning, Madam Chair, and thanks for having this hearing, and I appreciate the comments of the full committee chair regarding how this committee works with hearings

and then subcommittee hearings on legislation, and, of course, full committee markups, and I think that has been a hallmark of this committee, and I am glad to hear it will be that way going forward.

I wasn't going to say this, but given all the other discussion, it is important to note that the majority added a witness to this panel that we didn't find out about until after 5:00 on Friday.

And so, Mr. Davis, we thank you for joining us, because we reached out to you after that, because then we were given an opportunity, and it was sort of short notice, I know. But we appreciate your being here today.

Last Congress, as chairman of this committee, it was a priority of mine to make sure that patients could get streamlined access to more affordable prescription drugs. Working together in a bipartisan manner, the committee advanced the Food and Drug Administration Reauthorization Act, FADARA, to the full House, by unanimous vote, I might add, 54 to zero. The bill then went on to pass the House and, by voice vote, the Senate before being signed into law.

This law helps incentivize the entrance of competitive, generic drugs—I agree with the chairman, generics really matter—where there was a lack of competition in the marketplace, resulting in ability to decrease cost to consumers, and as a result, we have already seen generic drugs come to the market through these new pathways and prices begin to drop for consumers on a variety of medications. So I think the good work of the Energy and Commerce Committee again showing through.

In fact, according to the FDA, roughly 1,275 approvals and approximately 320 tentative approvals for generic drugs have occurred since passage of this law. This includes the approval of the first ever generic EpiPen, and we know what was involved around that. Even more, five competitive generic therapies approvals have taken place thanks to the new pathway granted to the FDA by this committee. And I would also say the work the committee did on the 21st Century Cures, as we heard yesterday from Secretary Azar, also allowed for more drugs to come to market sooner and more competition.

So I thank the former chairman, Mr. Upton, for his leadership, and Ms. DeGette as well.

The bipartisan law has lowered the cost of important medications and devices. It has sped up how medical innovations come to fruition, and this is a win for consumers. The real results are a bipartisan cooperative approach, and we didn't stop there.

We then turned our attention to the complete, drug-supply chain. We put together arguably, I think, one of the best bipartisan member briefings, as my tenure as chairman. For that briefing, we brought in an academic expert in drug pricing to better educate the members of the committee on the multifaceted problem and creative solutions to drive down the cost of prescription drugs.

Following that, we brought in ten witnesses, into a bipartisan hearing in this very room, where we dug into all aspects of the entire drug-supply chain. That included manufacturing, wholesale and distribution, and payment for drugs, and how each of these stages impacts the cost of medications. And they were all at that

table, and they couldn't point to somebody who wasn't because that person was there, too, and it really helped in our discussion.

Last Congress, our committee made real progress in getting lower-cost generics to market, incentivizing adding competition where it previously did not exist, examining the drug-supply chain, all because we worked together toward a common goal.

Regrettably, while Republicans share the goal of today's hearing—and we do—and some of these bills have bipartisan cosponsorship, and we do want to lower the cost of prescription drugs—we wish it were more inclusive. Today we are considering seven bills. Only three have Republican cosponsors. That is largely because we didn't get a list of these bills until just 8 days ago. And then we were given just 24 hours to help identify potential Republican cosponsors, and by my count, this subcommittee has reviewed 14 bills this Congress. Just four have Republican coauthors, and I know we can do better than that.

Equally concerning, the bills we are examining today each represent complex modifications of the Food, Drug, and Cosmetics Act, and the FDA is not serving as a witness. And I think we would benefit by their input, and certainly Dr. Gottlieb, who is leaving the FDA, was a terrific participant before this committee.

So I hope we will hear from the FDA along the process before the markup. Legislative hearing is the only public opportunity, though, to hear from experts on the policies being advanced, and we will not have the agency responsible for implementing such technical policies present.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Thank you, Madam Chair, for hosting today's hearing—the first regarding the issue of drug pricing under the new majority.

Last Congress, as chairman of this committee, it was a priority of mine to make sure that patients could get streamlined access to more affordable prescription drugs. Working together in a bipartisan manner, this committee advanced the Food and Drug Administration Reauthorization Act—or FDARA—to the full House by a unanimous vote of 54–0. The bill then went on to pass the House of Representatives by voice vote before being signed into law by President Trump.

This law helps incentivize the entrance of competitive generic drugs where there was a lack of competition in the marketplace, resulting in an ability to decrease costs to consumers. As a result, we've already seen generic drugs come to the market through these new pathways, and prices begin to drop for consumers on a variety of medications.

In fact, according to the FDA, roughly 1,275 approvals and approximately 320 tentative approvals for generic drugs have occurred since passage of this law. This includes the approval of the first ever generic EpiPen. Even more, five competitive generic therapies approvals have taken place thanks to the new pathway granted to the FDA by this committee.

This bipartisan law has lowered the costs of important medications and devices, sped up how medical innovations come to fruition, and is a win for our healthcare workforce.

These real results are the result of our bipartisan, cooperative approach.

And we didn't stop there. . .

We then turned our attention to the complete drug supply chain. We put together arguably the most well attended bipartisan member briefing of my tenure as chairman. For that briefing we brought in an academic expert in drug pricing to better educate our committee on this multifaceted problem and creative solutions to drive down the cost of prescription drugs.

Following that, we brought 10 witnesses into a bipartisan hearing in this very room where we dug into all aspects of the drug supply chain, including manufac-

turing, wholesale and distribution, and payment for drugs—and how each of these stages impact the cost of medications.

Last Congress, our committee made real progress in getting lower-cost generics to the market, incentivizing and adding competition where it previously didn't exist, and examining the drug supply chain—all because we worked together towards a common goal.

Regrettably, while Republicans share the goal of the today's hearing—lowering the cost of prescription drugs—the process has been anything but inclusive.

Today, we're considering seven bills, but only three have Republican cosponsors. That's largely because we didn't even get a list of these bills until just eight days ago. And then, we were given just 24 hours to help identify potential Republican cosponsors.

By my count, this subcommittee has reviewed 14 bills this Congress. Just four have Republican coauthors. That's a disturbing trend.

Equally concerning, the bills we are examining today each represent complex modifications to the Food, Drug, and Cosmetics Act and the FDA is not even serving as a witness. A legislative hearing is the only public opportunity to hear from experts on the policies being advanced, and we will not have the agency responsible for implementing such technical policies present.

Madam Chair, is there a reason we're not hearing from the FDA experts? Can you commit that this subcommittee will have an opportunity to get the agency's expert advice and counsel before members are required to vote on these bills?

I know you care deeply about getting public policy right, and we stand ready to work with on these important matters. American consumers need our help to get medical costs down and consumer choice up.

Mr. WALDEN. So with that, I am going to yield the balance of my time to Mr. Duncan.

Mr. DUNCAN. I thank the gentleman, and Madam Chairman, thank you for giving me the time and opportunity to be here today. It is an honor to introduce the President and CEO, and owner of Nephron Pharmaceuticals, and my good friend and fellow South Carolinian, Ms. Lou Kennedy.

Nephron Pharmaceuticals moved their headquarters to South Carolina in 2017 and employs over 600 people locally, all with a variety of skill sets. It is important to note that Lou is strongly supportive of our local veterans, all with a variety of skill sets. It is important to note—excuse me, Nephron hires a significant number of veterans as they are already primed to follow chain-of-command in the work environment. Lou is supportive of the University of South Carolina where Nephron recently established——

Ms. ESHOO. The gentleman's time is expired. I am sorry. Your time is expired. And we are glad that you are joining us today.

Mr. DUNCAN. I yield back.

Ms. ESHOO. Once again, welcome to all the witnesses. We have a very full table, and we are anxious to receive your testimony, and thank you for your written testimony. I want to remind Members that, pursuant to committee rules, all Members' written opening statements shall be made part of the record.

So we will start with Ms. Lou Kennedy, the CEO and owner of Nephron Pharmaceuticals. Welcome to you and make sure the mike is on——

Ms. KENNEDY. Thank you.

Ms. ESHOO. Ms. Kennedy, you have 5 minutes.

STATEMENTS OF LOU KENNEDY, CHIEF EXECUTIVE OFFICER AND OWNER, NEPHRON PHARMACEUTICALS; ANTHONY BARRUETA, SENIOR VICE PRESIDENT, GOVERNMENT RELATIONS, KAISER PERMANENTE; MICHAEL CARRIER, DISTINGUISHED PROFESSOR, RUTGERS LAW SCHOOL; KURT KARST, DIRECTOR, HYMAN, PHELPS & MCNAMARA, P. C.; JEFFREY P. KUSHAN, PARTNER, SIDLEY AUSTIN, LLP; MARC M. BOUTIN, CHIEF EXECUTIVE OFFICER, NATIONAL HEALTH COUNCIL; AND CHESTER "CHIP" DAVIS, JR., PRESIDENT AND CHIEF EXECUTIVE OFFICER, ASSOCIATION FOR ACCESSIBLE MEDICINES

STATEMENT OF LOU KENNEDY

Ms. KENNEDY. Good morning, Chairwoman Eshoo, Ranking Member Mr. Burgess, Chairman Pallone, and Ranking Member Walden, and distinguished members of the Energy and Commerce Subcommittee on Health. I want to thank you for this invitation to appear before you today to discuss competition to lower drug prices in the United States.

I am Lou Kennedy. I am CEO and owner of Nephron Pharmaceuticals Corporation. I am headquartered in West Columbia, South Carolina, and we have added more employees and have now reached a thousand employees. We are a leading manufacturer of sterile, genetic—generic medications, and we are sterile compounders of drugs on the FDA shortage list for all U.S. hospitals and surgery centers. High quality and affordable products for patients is our company focus.

Nephron believes drug patents should be controlled by a patent-approval system that reasonably rewards innovation but also incentivizes appropriate patent challenges, particularly for Orange Book-listed patents. A fair playing field would ensure erroneously granted patents are not used to prevent generic competition and maintain monopoly drug prices to the detriment of American consumers.

The Trump administration has published the American Patients First policy position which, if implemented, would encourage drug competition and reduce drug prices in the U.S. The American Patients First policy statement notes the negative impact of parking, the 180-day exclusivity awarded to eligible, first-to-file ANDAs, or abbreviated new drug applications.

Parking is the practice of delaying the introduction of a first-to-file ANDA, which goes directly against Hatch-Waxman Act, by entering into a delayed-entry settlement agreement between the ANDA filer and the original patent holder. This is commonly known as pay-to-delay. This is really an impediment to lowering the drug cost for Americans.

Nephron applauds this policy position for appropriate 180-day exclusivity, because of the immediate pricing reduction of second and follow-on suppliers of generic drug pricing.

Pricing data commonly demonstrates drug costs for a single med will drop approximately 80 percent when the fourth competitor enters the market. That is where we enter. Parking, along with Paragraph 4, patent challenges, and REMS program abuses add signifi-

cant delays to generic competition, there by maintaining higher monopoly drug prices.

Nephron shares the goal of this committee and the administration of addressing the problem of purposeful parking that delays generic competition from tentatively approved subsequently submitted ANDAs. However, while Nephron shares the goal of H.R. 938, Blocking Low Cost Operation—the BLOCKING Act of 2019, we are concerned as currently drafted the legislation would undermine the value of the 180-day exclusivity period.

This recent draft would prematurely terminate or reduce the first-to-file, 180-day exclusivity period by providing an overly broad, additional, exclusivity trigger that can result in forfeiture of the award. This outcome would not be in the best interest of American patients and taxpayers, and it would weaken this 180-day exclusivity incentive for generic manufacturers to drive challenges of brand patents.

The 180-day exclusivity period is important to allow the first filer to bring its product to market at the earliest possible time. We are also concerned that this well-intentioned legislation fails to address pay-to-delay settlements between a first-to-file generic company and its brand counterpart, which is the main source of delay for generic competition, particularly like us.

Nephron believes that pay-to-delay agreements allow weak, unchallenged patents to remain in place and serve as barriers to block subsequent, generic drug manufacturers from obtaining final approval. The current framework provides no incentive for subsequent applicants to challenge blocking patents that are left untested in pay-to-delay settlements.

Even if a subsequent applicant is successful in challenging all of the blocking patents, it cannot enter the market until a first applicant launches, allowing the 180-day exclusivity period to expire. Delaying the start of this period results in higher prices for a drug.

Now, the FAIR Generics Act, H.R. 1506, would achieve the needed broader fix of the parking problem by allowing subsequent applicants that win their patent challenges to share the 180-day exclusivity award with the first generic to file an application challenging a brand patent. As such, Nephron urges Congress to take action to fix the broader parking problem, not just a narrow subset of the problem, by enacting legislation, along the lines of the FAIR Generics Act.

We would welcome the opportunity with the committee to strengthen and refine this legislation, which would enable a comprehensive solution to the parking problem. The Trump administration, the committee, and Nephron are all in agreeance of the need to lower drug costs for the American public.

Nephron supports pending bills relating to ANDAs and the 180-delay exclusivity, some of which are directly related to H.R. 938, and others that are necessary to remove stumbling blocks for ANDAs being filed. The Protecting Consumer Access to Generic Drugs of 2019 aims to prevent pay-to-delay settlements between first applicants and brand companies by adding a clause, exchange of anything of value, to current laws which prevents money from being exchanged for delayed marketing under a parked, 180-day exclusivity situation.

Ms. ESHOO. Your time is expired.

Ms. KENNEDY. Thank you. I would entertain any questions from the panel.

[The prepared statement of Ms. Kennedy follows:]

TESTIMONY OF
LOU KENNEDY
CHIEF EXECUTIVE OFFICER

NEPHRON PHARMACEUTICALS

Before the

UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY & COMMERCE SUBCOMMITTEE ON HEALTH

March 13, 2019

Chairwoman Eshoo, Ranking Member Dr. Burgess, and distinguished members of the Energy & Commerce Subcommittee on Health, I want to thank you for the invitation to appear before you today to discuss competition to lower drug prices in the United States.

My name is Lou Kennedy and I am the CEO of Nephron Pharmaceuticals Corporation ("Nephron"), proudly headquartered in West Columbia, South Carolina. Nephron employs 1000 people and is a leading manufacturer of sterile generic medications and the compounding of drugs on the FDA shortage list for US hospitals and surgery centers. High-quality and affordable products for patients is the company focus.

Nephron believes drug patents should be controlled by a patent approval system that reasonably rewards innovation, but also incentivizes appropriate patent challenges, particularly for Orange-book listed patents. A fair playing field would ensure erroneously granted patents are not used to prevent generic competition and maintain monopoly drug prices to the detriment of American consumers.

The Trump administration has published the "American Patients First" policy position which if implemented, would encourage drug competition, and reduce drug prices in the United States. The "American Patients First" policy statement notes the negative impact of "parking" the 180-day exclusivity awarded to eligible "first-to-file" abbreviated new drug applications or "ANDAs". Parking, is the practice of delaying the introduction of a first-to-file ANDA by entering into a delayed entry settlement agreement between the ANDA filer and the original patent holder, this is commonly known as a "pay-to-delay" settlement.

Nephron applauds this policy position because of the immediate pricing reductions of second and follow-on suppliers of a generic drug. Pricing data commonly demonstrates drug costs for a single medication, will drop approximately 80% when the fourth competitor enters the market. Parking along with Paragraph IV patent challenges, and REMS program abuses, add significant delays to generic competition, thereby maintaining higher monopoly drug prices.

Nephron shares the goal of the Committee and the Administration of addressing the problem of purposeful parking that delays generic competition from tentatively-approved, subsequently-submitted ANDAs. However, while Nephron shares the goal of H.R. 938 ("Blocking Low-Cost Operations and Competition while Keeping Incentives for New Generics Act of 2019" or the "BLOCKING ACT of 2019") we are concerned as currently drafted, the legislation would undermine the value of the 180-day exclusivity period. This recent draft would prematurely terminate or reduce the first-to-file ANDA 180-day exclusivity period, by providing an overly-broad additional exclusivity "trigger" that can result in forfeiture of the award. This outcome would not be in the best interests of patients and taxpayers, as it would weaken the 180-day exclusivity incentive for generic manufacturers to drive challenges of brand patents.

The 180-day exclusivity period is important to allow the first-filer to bring its product to market at the earliest possible time. We are also concerned that this well-intentioned legislation fails to address pay-to-delay settlements between a first-to-file generic company and its brand counterpart, which is the main source of delays for generic competition.

Nephron believes that pay-to-delay agreements allow weak, unchallenged patents to remain in place, and serve as barriers to block subsequent generic drug manufacturers from obtaining final approval. The current framework provides no incentive for subsequent applicants to challenge blocking patents that are left untested in pay-to-delay settlements. Even if a subsequent applicant is successful in challenging all of the blocking patents, it cannot enter the market until a first applicant launches, allowing the 180-day exclusivity to expire. Delaying the start of a 180-day exclusivity period, results in higher prices for a drug.

The FAIR Generics Act, HR 1506, would achieve the needed broader fix of the parking problem by allowing subsequent applicants that win their patent challenges to share the 180-day exclusivity award with the first generic to file an application challenging a brand patent(s). As such, Nephron urges Congress to take action to fix the broader parking problem, not just a narrow subset of the problem, by enacting legislation along the lines of the FAIR Generics Act. We would welcome the opportunity to work with the Committee to strengthen and refine the legislation, which would enable a comprehensive solution to the parking problem. The Trump Administration, the Committee, and Nephron are all in agreeance of the need to lower drug costs for the American public.

Nephron supports pending bills related to ANDAs and the 180-day exclusivity—some which are directly related to H.R. 938, and others that are necessary to remove stumbling blocks for ANDAs being filed. The "Protecting Consumer Access to Generic Drugs Act of 2019" aims to prevent pay-to-delay settlements between first applicants and brand companies, by adding the clause "exchange of anything of value" to current laws which prevents money from being exchanged for delayed marketing under a parked 180-day exclusivity situation. Nephron believes it is important for there to be agreement options, other than money, for first applicants to settle with brand companies. If there is any agreement between the patent holder and the first-to-file, there should always be options to incentivize for subsequent applicants, which would challenge Orange Book patents as just discussed.

Nephron recognizes this brand gamesmanship is still a problem when generic and biosimilar companies attempt to obtain samples for branded products with restricted distribution, or join in FDA-mandated Risk Evaluation and Mitigation Strategies known as "REMS" with Elements To Assure Safe Use, "ETASU". ETASU REMS include measures such as patient testing, special physician training or certifications, and restricted distribution, the latter which has been exploited to prevent or delay generic market entry. FDA requires shared REMS only for ETASU REMS. ETASU REMS products enjoy extended monopolies, because branded companies have blocked samples and shared REMS entry using unfounded concerns for patient safety with generic products as a block for access to reference samples necessary for product development, testing, and approval. Nephron therefore supports the CREATES ACT (H.R. 965) and FAST Generics Act (H.R. 985), because both promote accessibility of reference product samples, particularly when they are marketed under restricted distribution. In addition, the bills would facilitate the development of shared ETASU REMS.

Nephron believes drug patent work should be carried out by appropriate patent attornies, but does lend general support to two bills aimed at generating and publishing additional product information helpful to the development of generic and biosimilar medicines, the Orange Book Transparency Act of 2019 ("Orange Book Act") and the Purpose Book Continuity Act of 2019 ("Purple Book Act"). The Orange Book Act would, among other things, require additional yet pertinent exclusivity information to be added to the Orange Book, along with including additional patent information, including the status of post-grant proceedings and litigations. The Purple Book Act would require listing certain asserted patent information and bioequivalence information, which would aid in the selection and development of biosimilar products. Keep in mind these compendiums are great aids, but patent search work reveals the ultimate information.

Nephron thanks the Committee for the opportunity to comment on these bills affecting generic and biosimilar product development and looks forward to working with the Committee to refine any of the bills that move forward for full House or Senate votes.

Ms. ESHOO. Thank you very much for your testimony and your written testimony.

Mr. Davis, good morning.

Mr. DAVIS. Good morning.

Ms. ESHOO. And welcome to you. You have 5 minutes to present your testimony to the committee.

STATEMENT OF CHESTER "CHIP" DAVIS, JR.

Mr. DAVIS. Great. Chairman Eshoo, Ranking Member Burgess, Chairman Pallone, Ranking Member Walden, thank you on behalf of the Association for Accessible Medicines, our members, and the patients that we serve, for the invitation and opportunity to testify today.

Over the last decade, our members have delivered savings of nearly $1.8 trillion to patients in the U.S. healthcare system, and looking forward, FDA-approved biosimilars have the potential to provide even greater savings and access to live-saving treatments. However, current market realities and certain anticompetitive tactics that impede competition, threaten the long-term stability of both the generic and biosimilar markets here in the United States.

So as Congress considers steps to lower prescription-drug prices, we encourage this committee to advance policies that increase competition and patient access to generics and biosimilars. Equally important, however, is to avoid policies that could, despite best intentions, end up further delaying such competition and access, and address the very real sustainability challenges faced by generic and biosimilar manufacturers here in the U.S. market.

To some of the specifics on the bills before you today, AAM greatly appreciates the leadership of Chairman Pallone, Congressman Welch, and Congressman McKinley on the CREATES and FAST Generics Acts. With the support of more than now 90 organizations, these strongly bipartisan, market-based solutions will stop anti-competitive abuses of FDA safety programs and reduce spending on prescription drugs by over $13 billion annually.

AAM strongly supports the CREATES and FAST Generics Act and encourages Congress to pass them into law immediately. AAM and our members value innovation and intellectual property, and the benefits that they provide to patients in the U.S. healthcare system. That said, it is equally important to recognize that perhaps the greatest barrier to competition occurs due to abuses of the U.S. patent system.

Increasingly, brand name companies are building so-called, quote, "patent estates," end quote, around blockbuster drugs. In fact, recent research shows that at least 78 percent of new patents are associated with existing drugs that are already on the market.

If Congress is going to meaningfully reduce drug prices, addressing abuse of the patent system must be front and center. To that end, we recommend three solutions: First, to provide a date certain for generic and biosimilar entry; second, to accelerate the biosimilar patent dance; and third, to harmonize Hatch-Waxman with the IPR process.

Despite the deterrent effect of brand name drug-patent thickets, a patent challenge and a potential settlement of that challenge is

increasingly the only way a generic or biosimilar manufacturer can actually bring a competitive medicine to patients.

Thus, it is imperative to make sure, as these bills are deliberated, that two critical elements are preserved: First, the right of two private parties to reach a settlement that is procompetitive, that brings generic drugs and biosimilars to market prior to the expiration of applicable patents; and second, the 180-day exclusivity period provided to the first generic filer.

Since the Supreme Court's decision in *FTC* v. *Actavis*, the FTC has reported that there are now very few patent settlements involving what is characterized as, quote, "pay-for-delay," end quote. In fact, the vast majority of patent settlements are now resolved without a transfer of value, since that decision, to the generic manufacturer or restrictions on generic competition.

It is our view that the patent-settlement legislation under consideration today is not yet quite aligned with the Supreme Court's Actavis decision. Moreover, the FTC is not required in the current bill to establish anticompetitive harm. As a result, we recommend that the proposal be narrowed to preserve agreements that are procompetitive, while making sure that those that are anticompetitive are held to account.

Patients and taxpayers also benefit when generic manufacturers take on significant risks and costs associated with being the first to file with the FDA and challenge a brand-name patent. The 180-day exclusivity incentive for first generics has helped fuel the growth of the American, generic drug market that today provides 90 percent of prescriptions for just 23 percent of drug spending, numbers that are unparalleled anywhere in the world.

Chairwoman, thank you for recognizing that earlier.

Importantly, Congress prohibited so-called parking as part of the Medicare Modernization Act. The FDA has the authority to address this issue, and despite our requests, we have not been provided any examples yet, to date, to justify the legislative proposals and changes. For these reasons, at this point, recognizing that this is a fluid process, AAM is not supporting the legislation that would prohibit patent settlements or changes to the 180-day exclusivity for first generics, recognizing that this is a process.

In our view, while well-intentioned, these proposals have the risk of ending up delaying patient access to more affordable generics and biosimilars.

So let me close by thanking the committee for the opportunity to testify today and say that our members stand ready to work with you to ensure patients have access to generics and biosimilars. Thank you.

[The prepared statement of Mr. Davis follows:]

Association for Accessible Medicines
Statement of Chester "Chip" Davis, Jr.
House Energy and Commerce Subcommittee on Health
Hearing on "Lowering the Cost of Prescription Drugs:
Reducing Barriers to Competition"
March 13, 2019

Competition is a Proven Solution to Lowering Drug Costs

Chairwoman Eshoo, Ranking Member Burgess, Chairman Pallone, Ranking Member Walden and the members of the Energy and Commerce Health Subcommittee, thank you for the invitation to testify today. I am Chip Davis, President and CEO of the Association for Accessible Medicines (AAM). AAM is the nation's leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. Our members provide more than 36,700 jobs at nearly 150 facilities and manufacture more than 61 billion doses in the United States every year. AAM's core mission is to improve lives by advancing timely access to affordable generic and biosimilar medications.

I commend you for holding today's legislative hearing on the importance of reducing barriers to competition in order to the lower the cost of prescription drugs. Increasing competition in the prescription drug market – especially with the introduction of more affordable generic and biosimilar medicines – is a proven solution to delivering savings at the pharmacy counter for patients, and this hearing represents an important step toward identifying and advancing meaningful solutions to that end.

Generic medicines play an integral role in health care and enhance patient access to life-saving treatments. The expiration of patents and the introduction of multiple generic manufacturers competing against each other on price results in significant savings for patients and the health care system. Over the last 10 years, generic manufacturers have delivered savings of nearly $1.8 trillion – including $265 billion in 2017 – to patients and the health care system.[1]

Biosimilar medicines represent another critical step forward in reducing high drug prices. Biosimilars are safe, effective and more affordable versions of costly brand biologics. By the year 2025, over 70 percent of drug approvals are expected to be biological products.[2] Experts estimate that FDA-approved biosimilars could save more

[1] AAM, "Generic Drug Access & Savings Report 2018," July 2018.
[2] U.S. Pharmacist, "Biosimilars: Current Approvals and Pipeline Agents," October 2016.

than $54 billion over the next 10 years.[3] In doing so, biosimilars will mean greater access to lifesaving cures for an estimated 1.2 million patients.[4]

However, the sustainability of a competitive generic market and the availability of generic medicines for patients, uninterrupted by shortages, is in jeopardy. Current market realities and anti-competitive tactics, combined with misguided policies, threaten the long-term stability of the generics and biosimilars markets. As we outlined in the February 2018 whitepaper, "Ensuring the Future of Accessible Medicines in the U.S.," generic and biosimilar manufacturers are facing an increasing set of challenges to getting new competitive and more affordable medicines to market and to ensuring patient access to generic medicines on the market continues without interruption.

Today's legislative hearing addresses one of the challenges: the gaming of FDA's safety programs to delay generic and biosimilar entry. However, there are many significant barriers to competition – for example, abuse of the patent system to extend high-priced monopolies, which I will discuss in more detail – and punitive policies – such as the Medicaid Generics Penalty – that impose unpredictable, onerous penalties on generic medicines that undermine patient access to life-saving medicine. Thus, it is critical for Congress to advance policies that increase competition from generic and biosimilar medicines, while avoiding policies that further delay patient access to more affordable treatments, and to also take action to address the very real sustainability challenges faced by generic and biosimilar manufacturers.

Brand-Name Drugs Increase Costs, Generic Medicines Drive Savings

Brand-name drugs comprise only 10 percent of prescriptions filled annually by patients, but now constitute 77 percent of all spending on prescription drugs.[5] Specialty medicines (including brand biologics) are rapidly approaching half of all spending despite being used by fewer than 3 percent of patients.[6] Encouraging competition and patient adoption of more affordable generic and biosimilar medicines is a critical component of lowering patient out-of-pocket spending.

The introduction of generic and biosimilar competition significantly reduces the price of medicine, and patients benefit from greater, more affordable access to FDA-approved drugs. Experience shows prescription drug prices decline by more than half the first-year generics enter the market.[7] Early experience with the nascent biosimilars market in the U.S. also shows that these more affordable alternatives are also providing value and savings to patients, on average priced 40 percent lower than their branded biologic counterparts.[8]

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[3] RAND, "Biosimilars Cost Savings in the United States," October 2017.
[4] The Biosimilars Council, "Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines," August 2017.
[5] Ibid., AAM.
[6] IQVIA, "Medicine Use and Spending in the U.S.," April 2018.
[7] IMS Institute for Healthcare Informatics, "Price Declines after Branded Medicines Lose Exclusivity in the U.S.," January 2016.
[8] AAM analysis of IQVIA WAC Data, December 2018.

Unfortunately, the ability of biosimilars to fulfill their potential is threatened by market abuses by brand-name drug companies and misguided policies that block access to lower-cost medicines. Seventeen biosimilars are now approved in the U.S., yet only seven are on the market and available to patients.[9] In comparison, more than 50 biosimilars are available to patients in Europe.

It is sobering to consider what America's patients would face if there were no FDA-approved generic or biosimilar medicines to provide reliable access to affordable treatments. Generics not only deliver the most medicine at the lowest cost and the greatest savings. Generic medicines also cushion the significant impact dealt to patients and the health care system by high brand-name drug prices every day. Put another way, the availability of low-cost generics offsets the impact of high brand-name drug prices.

CREATES/FAST Generics End the Abuse of FDA's Safety Rules

For these reasons, AAM greatly appreciates the leadership of Chairman Pallone, Congressman Welch, Congressman McKinley and their bipartisan cosponsors on the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 (H.R. 965/ S. 340) and the Fair Access for Safe and Timely (FAST) Generics Act of 2019 (H.R. 985). The CREATES and FAST Generics Acts lower the cost of prescription drugs for patients through increased competition and by stopping the abuse of FDA's safety programs and non-FDA mandated closed distribution systems. With the support of more than 90 organizations, these bipartisan, market-based solutions will reduce spending on prescription drugs by an estimated $13.4 billion each year.[10] **AAM strongly supports the CREATES and FAST Generics Acts.** Congress should immediately pass the CREATES and FAST Generics Acts and enact these solutions into law.

Generic and biosimilar manufacturers face significant challenges obtaining the samples needed for generic or biosimilar development. This is a result of the misuse of FDA's rules designed to ensure the safety of medicines by certain brand-name drug companies focused on delaying or prevent competition. Abuse of FDA-mandated safety programs occurs when brand-name drug companies, using a Risk Evaluation and Mitigation System (REMS) or their own voluntary "safety" program as an excuse, refuse to sell brand-name doses to generic and biosimilar manufacturers at fair market value. These doses are necessary for generic and biosimilar manufacturers to conduct bioequivalence testing. Without the ability to purchase samples, generic and biosimilar manufacturers are unable to seek FDA approval and deliver more affordable, alternative medicines to patients.

In addition, brand-name drug companies establish non-FDA mandated closed distribution systems. These arrangements often restrict the ability of generic and

[9] FDA, FDA-Approved Biosimilar Products, January 2019.
[10] Brill, Alex, "Unrealized Savings from the Misuse of REMS and Non-REMS Barriers," September 2018.

biosimilar manufacturers to purchase brand-name doses and this serves as another obstacle to competition. FDA has noted that closed distribution systems lack transparency and a clear benefit to patients.

Generic and biosimilar manufacturers are also challenged by brand-name drug companies' refusal to negotiate in good faith on the creation and implementation of a single-shared REMS system (SSRS). Current law stipulates that a generic medicine must utilize a single-shared system along with the brand-name drug unless FDA waives this requirement for one of the reasons set forth in the statute.

AAM and its member companies believe that patients and providers benefit from a shared system. In fact, the creation of a single-shared REMS system should be relatively straightforward and simple; however, brand-name drug companies regularly use a variety of tactics to delay and extend negotiations. This refusal to engage in good faith negotiations can delay the approval of the generic product and force consumers to pay more to fill their prescriptions.

Last year, and updated recently, the FDA published a list of over 170 instances where access to samples has been at issue.[11] The FDA's list covers 55 unique medicines. Brand-name drug companies with the highest number of products and inquiries are: Celgene (recently acquired by Bristol-Myers Squib) with three products (Pomalyst®, Revlimid®, and Thalomid®) with 31 complaints; Actelion Pharmaceuticals (a subsidiary of Johnson & Johnson) with four products (Opsumit®, Tracleer®, Veletri®, and Zavesca®) with 26 complaints; and, Gilead with two products (Letairis® and Truvada®) with 11 complaints.[12] While FDA's leadership in shining a light on this abusive practice is welcome, the data is alarming: the number of inquiries and the products they cover is an indication that the practice continues to grow.

The CREATES and FAST Generics Acts would end these abuses and facilitate patient access to new, more affordable FDA-approved generic and biosimilar medicines. Under the CREATES and FAST Generics Acts, the FDA's current processes, oversight and approval process would be maintained; patient safety would be further enhanced by codifying the FDA's current guidance on the safe handling of samples into law; and, comparable protections for safety systems, as determined by the FDA, would be in place.

In addition, a limited legal pathway is made available only in instances when the FDA has ensured the appropriate safeguards are in place and a brand-name drug company continues to unjustifiably deny the purchase of samples.[13] If the doses are available for purchase, there is no opportunity for a generic manufacturer to bring a claim. Further, brand-name drug companies are provided with an affirmative defense for which one only needs to show that the doses are available for purchase on market-based terms and that no restrictions are in place that would prevent sale of the brand-name doses.

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[11] FDA, "Reference Listed Drug (RLD) Access Inquiries," Published May 2018, Updated February 2019.
[12] AAM analysis of FDA's RLD Access Inquiries List, March 2019.
[13] Kirkland & Ellis, "The CREATES Act (S. 974/H.R. 2212) – Legal Analysis of Criticisms," March 2018.

Abuse of the Patent System Delays Generic and Biosimilar Competition

Perhaps the greatest barrier to increased prescription drug competition occurs due to abuses of the U.S. patent system, and AAM applauds Chairman Pallone's recent remarks at the launch of the Coalition Against Patent Abuse (CAPA). While AAM's member companies strongly support innovation, they are finding it increasingly challenging to deliver new, more affordable generic, and especially biosimilar, medicines to patients due to patent abuse.[14]

In my testimony to this Subcommittee in December 2017, I explained how abuse of the patent system to prolong a brand-name drug's monopoly – a practice commonly referred to as "evergreening" – is increasingly being used as a delay tactic. These anti-competitive practices run counter to Congress's stated goal of bringing lower cost generic and biosimilar alternatives to market at the earliest possible date certain.[15] The problem, unfortunately, has only gotten worse since then and, without action to curtail these practices, patients will continue to pay monopoly prices for brand-name drugs and biologics.

Recent research demonstrates the extent of the problem and the increased costs borne by patients. Increasingly, brand-name drug companies are building patent "estates" around their drugs, not just for the original innovative research, but for much smaller changes that may not be deserving of decades-long monopolies. At least 78 percent of the new patents in the FDA's Orange Book are associated with *existing* drugs on the market.[16] Moreover, of the roughly 100 best-selling drugs, more than 70 percent obtained a patent that extended the monopoly period beyond the duration of the initially-granted patent. [17]

Moreover, a recent report from I-MAK, examined the top 12 brand-name drugs on the market and found that a total of 848 patents (71 per drug) shield these medicines from generic and biosimilar competition for an average of 38 years.[18] A few examples from the report demonstrate how patent thickets are established on these blockbuster drugs:

- The world's top-selling brand-name drug, Humira®, treats arthritis and other chronic conditions. On the market since 2002, 132 patents block competition for up to 39 years.[19] The price of Humira increased 144 percent since 2012.[20]

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[14] AAM, "Ensuring the Future of Accessible Medicines in the U.S. – Ensuring Competition for America's Patients," February 2018.
[15] AAM, Statement of Chester "Chip" Davis, Jr. to the Energy and Commerce Health Subcommittee, Hearing on "Examining the Drug Supply Chain," December 2017.
[16] Feldman, Robin, "May Your Drug Price Be Evergreen," December 2018.
[17] Ibid.
[18] I-MAK, "Overpatented, Overpriced," August 2018.
[19] Ibid.
[20] Ibid.

- One of the most prescribed cancer treatments, Revlimid®, was approved by the FDA in 2005. The patent thicket consists of 96 patents providing potentially 40 years without competition.[21] The price of Revlimid increased 79 percent since 2012.[22]

- Diabetes patients who rely on the insulin treatment, Lantus®, may not see a generic alternative for 37 years due to the 49 patents issued.[23] The price of Lantus increased 114 percent since 2012.[24]

In these instances, branded biologic manufacturers are attempting to accumulate patents not because they are innovative, but rather to increase litigation and development costs for potential would-be generic and biosimilar competitors.

Addressing abuse of the patent system must be front-and-center if Congress is effectively going to reduce drug prices for patients.

Improving Patent Transparency in the Orange and Purple Books

AAM appreciates the Subcommittee's work to improve transparency to the patents obtained on brand-name prescription drugs in the Orange and Purple Books published by the FDA. In recommendations to the Department of Health and Human Services (HHS) on the *Blueprint to Lower Drug Prices* in July 2018, we recommended that the FDA separately identify formulation changes as different products under the approved brand-name drug and reflect discontinued products in the Orange Book.[25] We also encouraged the FDA to list patent information for brand-name drugs approved prior to 2013 upon request.[26] In addition, the FDA should update the Purple Book to provide clarity around the exclusivity periods (unexpired and pending) for brand-name biologics, include interchangeability guidance, and improve its functionality by making it a searchable, electronic database.[27]

Collectively, these improvements to the Orange and Purple Books could facilitate more timely generic and biosimilar applications and entry into the market. With improved transparency, generic and biosimilar manufacturers can accurately assess the patents and exclusivities applied to brand-name drugs and determine for which products to prepare applications for approval. Without this information, generic and biosimilar competition is impeded as brand-name drug companies bring lawsuits seeking to stop FDA approval of competitive products due to undisclosed patents.

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[21] Ibid.
[22] Ibid.
[23] Ibid.
[24] Ibid.
[25] AAM Comment Letter, HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, July 2018 (page 33).
[26] Ibid (page 34).
[27] Ibid (pages 28-29).

The Orange Book Transparency Act of 2019 (H.R. 1503) and the Purple Book Continuity Act of 2019 (H.R. 1520) include steps to improve patent transparency and disclosure. The Orange Book Transparency Act directs the FDA to include information on patents related to the drug, drug substance, drug product, and method of use. Unexpired exclusivities shall also be specified. FDA would also be directed to promptly remove invalid patents due to a Patent Trial and Appeal Board (PTAB) or court decision. The Purple Book Continuity Act directs the FDA to ensure the Purple Book includes the name, date of licensing, and type of bioequivalence study to be publicly listed and updated monthly. In addition, patent information would be listed if provided by a brand-name drug company to a biosimilar (351(k)) applicant.

AAM supports the Orange Book Transparency Act and the Purple Book Continuity Act, and recommends additional transparency and disclosure requirements consistent with our comment letter to HHS be included.

Preserving the Ability to Challenge Patents and Increase Patient Access to Generics and Biosimilars

Challenging potentially non-innovative patents is an expensive endeavor without any guarantee of success. Some have estimated litigation expenses on the order of $1 million per patent. When one considers the patent thickets established around the top-selling brand-name drugs as described earlier, it is fair to question whether patients will in a timely manner be able to benefit from competition from more affordable, FDA-approved generics and biosimilars.

Seemingly impenetrable thickets of patents cannot be overcome by generic or biosimilar manufacturers in a single patent litigation. For example, Humira® – one of the most expensive drugs in America – is now protected by a thicket of more than 100 patents, with the potential for that thicket to grow to over 200 patents.[28] The expiration of the last patent on file is 2034.

Despite the deterrent effect of patent thickets, a patent challenge is increasingly the only way a generic or biosimilar manufacturer can begin the process of bringing a competitive generic product to patients. However, in order to do so, there are two critical elements to achieving successful generic entry – the right of two private parties to reach a settlement providing for competition earlier than the expiration of the last patent and the 180-day exclusivity period provided to the first filer generic manufacturer that is able to successfully challenge a patent and reach the market.

Patent Settlements Expedite Patient Access to Generics

Patent litigation settlements can produce numerous additional pro-competitive benefits that benefit patients. For example, one study has found that settlements lead to generic

[28] Ibid., I-MAK.

entry, on average, 81 months (6.75 years) *prior to* patent expiry.[29] That early entry has created enormous value for consumers – one generic manufacturer estimated in 2009 that its settlements had removed 138 years of monopoly protection through early generic entry.[30] In addition to these direct, bottom-line benefits, settlements also avoid additional expensive, burdensome litigation costs.[31]

Settlements also provide generic and biosimilar companies with essential pro-competitive benefits that could not be achieved through expensive, years-long litigations. In addition to patent monopolies, drug products are subject to regulatory exclusivities that prevent the FDA from approving generic drug applications. Thus, even if a generic manufacturer believes it can invalidate the brand-name drug's patents, it may still be blocked from launching its product through a regulatory exclusivity. That barrier to entry is almost always addressed in a settlement agreement via a regulatory waiver – a waiver that cannot be achieved via litigation or by other means. Without such a waiver, generics cannot get approval to launch their products before the expiration of regulatory exclusivities.

Patients benefit from generic competition when a pro-competitive patent litigation settlement is achieved. Unfortunately, so-called "pay-for-delay" patent settlement legislation would overturn the Supreme Court's 2013 decision in *Federal Trade Commission (FTC) v Actavis* and outlaw pro-competitive settlements that benefit patients. Given the benefits of pro-competitive settlements, we recommend the "pay-for-delay" proposals be modified to preserve the ability of brand-name and generic companies to continue to settle their disputes, consistent with the *Actavis* decision and provide for substantial consumer cost-savings through timely generic entry.

180-Day Exclusivity Encourages Competition, First Generics for Patients

For more than 30 years, the Hatch-Waxman Act has provided the only incentive for generic manufacturers to be the first to market by awarding a 180-day period of exclusivity for first filers that challenge a patent protecting an expensive brand-name drug. By promoting patent challenges, 180-day exclusivity encourages earlier entry of safe and effective generic alternatives that are less expensive than the brand. Thus, the 180-day exclusivity provision has been critical to the Hatch-Waxman Act's track record of success in promoting generic competition.

Weakening the 180-day period of exclusivity for first generics will ensure that more non-innovative brand-name drug patents remain in place, delaying the availability of generic medicines for patients. As a result, patients will pay high brand-name drug prices for longer without competition from more affordable FDA-approved generic medicine.

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[29] Patent Docs, "IMS Study Shows Pro-Competitive Effects of Reverse Payment Settlement Agreements in ANDA Litigation," July 2013.
[30] Teva, Statement in Response to Federal Trade Commission Claims on Patent Settlements, June 2009.
[31] *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 629 F.3d 1374, 1376–77 (Fed. Cir. 2011) and Herman, Note, "The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation," 2011.

Moreover, no evidence has been provided to date to justify any changes to the 180-day exclusivity for first generics. Concerns about the potential for "parking" of applications were adequately addressed by Congress as part of the Medicare Modernization Act of 2003. FDA's current statutory and regulatory authority allow the agency to conclude that 180-day exclusivity will not be awarded to a first applicant that does not diligently pursue approval. Specifically, current FDA regulations state: "If FDA concludes that a first applicant is not actively pursuing approval of its ANDA, FDA may immediately approve an ANDA(s) of a subsequent applicant(s) if the ANDA(s) is otherwise eligible for approval."[32] Hence, both Congress and FDA have already solved for alleged "parking" of generic exclusivity.

For these reasons, **AAM opposes the Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act (H.R. 938), the Protecting Consumer Access to Generic Drugs Act (H.R. 1499), and the Fair Access for Safe and Timely (FAIR) Generics Act (H.R. 1506) as introduced.** Unfortunately, these proposals, as drafted, would have the unintended impact of *reducing* generic and biosimilar competition in the prescription drug market and thus lead to patients paying the high-cost of brand-name drugs for longer.

We are ready and willing to work with the Subcommittee to increase competition and enhance patient access to more affordable FDA-approved generics and biosimilars. AAM supports and encourages the Energy and Commerce Committee to consider several policies that would allow for expeditious challenge of brand-name drug patent thickets. For example, we recommend:

- *Providing a Date Certain for Generic and Biosimilar Entry.* Congress rewards brand-name drug companies with a set period for monopoly protection, and upon expiration of that time period, competition should begin. Congress could take steps to kick-start biosimilar competition by, for example, ensuring that patents do not impede competition beyond the 12-year term of market exclusivity.

- *Accelerate the Biosimilar "Patent Dance."* Congress could allow for the initiation of patent litigation at the point when a biosimilar developer has a Type III development meeting with the FDA. This would accelerate the timeline and permit biosimilars to be marketed sooner, speeding their cost-savings to patients.

- *Harmonize Hatch-Waxman with Inter-Partes Review (IPR).* A 30-month stay on the FDA's approval of a generic drug application is imposed under Hatch-Waxman and only dissolved when a court decision finds the asserted Orange Book patents are invalid or not infringed. Congress could update Hatch-Waxman to reflect the current market realities by not allowing a patent that has been held invalid in an IPR to be the basis for a 30-month stay on FDA approval.

[32] 21 C.F.R. § 314.107(c)(3).

We will gladly work with the Subcommittee and its members on these solutions, as well as other policy ideas we have put forth, to address the high price of patent abuse – a price that is ultimately borne by patients who are without alternatives when there is no FDA-approved, more affordable generic or biosimilar medicine on the market and competition is delayed for decades.

Conclusion

Independent research and data demonstrate one undeniable conclusion: Brand-name drug prices continue to rise, while generic drug prices continue to fall. With brand-name drugs accounting for 77 percent of total spending on prescription drugs in 2017, the high cost of many prescriptions is often out of reach for patients.[33] Higher spending on prescription drugs impacts everyone – directly in the form of higher premiums and out-of-pocket costs and as taxpayers to cover the costs of Medicare, Medicaid, and other federal health care programs. Prescription drugs now account for $0.23 out of every premium dollar and the average co-pay for brand-name drugs was $40.30 in 2017.[34] [35]

In contrast, the amount spent on generic medicines has declined for the last 30 consecutive months.[36] Nine out of every 10 prescriptions filled in the U.S. are for generic drugs and spending on generic drugs accounted for only 23 percent of total prescription drug spending.[37]

Savings from generic and biosimilar medicines, however, often go unrealized. HHS found "incompletely aligned incentives for generic substitution leave significant savings uncaptured."[38] Seniors and the Medicare Part D program would have saved $3 billion in 2016 if generics had been dispensed rather the brand-name drug.[39] Last year, the FDA reported that patients could have saved "more than $4.5 billion in 2017" if they had the ability to purchase FDA-approved biosimilars.[40]

Moreover, new analysis from Avalere shows generic drugs are increasingly being placed on higher formulary tiers for seniors with Medicare Part D coverage. From 2011 to 2019, the number of generic drugs on Tier 1 (Preferred Generic) has declined from 71 percent to 14 percent.[41] Generic drugs are now placed on Tier 3 (Preferred Brand) 18 percent of the time and Tier 4 (Non-Preferred Drug) 25 percent of the time.[42] As a result, patients are shouldering more of the out-of-pocket costs for the same drugs at

[33] Ibid.
[34] America's Health Insurance Plans (AHIP), "Where Does Your Health Care Dollar Go?," May 2018.
[35] Ibid., AAM.
[36] Morgan Stanley, Monthly YOY Generic Prescription Drug Sales, January 2019.
[37] Ibid., AAM.
[38] HHS, "Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D," January 2018.
[39] Ibid.
[40] FDA, Remarks from FDA Commissioner Scott Gottlieb, M.D., FDA's Biosimilars Action Plan, September 2018.
[41] Avalere, "Effect of Potential Policy Change to Part D Generic Tiers on Patient Cost Sharing and Part D Plan Costs," February 2019.
[42] Ibid.

the same price. Avalere found "patient cost-sharing would have been $15.7 billion lower" over the last four years if generic medicines were placed only on generic formulary tiers.[43]

The Centers of Medicare and Medicaid Services (CMS) – with the support of Congress – could take immediate action to lower the out-of-pocket costs for seniors with Medicare coverage by adopting the "Generics on Generic Tiers" proposal for 2020. If finalized, Avalere estimates seniors would save $4 billion a year in prescription drug costs.[44]

Efforts to ensure patients are able to fully realize the savings available from generic and biosimilar medicines on the market today combined with Congressional action to advance policies that increase competition is the ultimate equation to achieving the shared goal of enhancing patient access to more affordable generic and biosimilar medicines.

AAM greatly appreciates the attention and work of the Energy and Commerce Committee and the Health Subcommittee to address many of the barriers to competition that are delaying or altogether preventing patient access to more affordable medicines. We look forward to continuing to work with you to advance the CREATES/FAST Generics Acts, curtail the undeniable abuse of the patent system, increase transparency of patents in the Orange and Purple Books, and preserve the ability of generic and biosimilar manufacturers to challenge patent thickets. Thank you for considering our views.

[43] Ibid.
[44] Ibid.

Ms. ESHOO. Thank you very much, Mr. Davis.

And now it is a pleasure to welcome and recognize Mr. Anthony Barrueta, the senior vice president of government relations at Kaiser Permanente, the first HMO in our country, correct?

Mr. BARRUETA. Pretty close. Pretty close.

Ms. ESHOO. 1942, I think.

Mr. BARRUETA. We have been around for a long time, so thank you.

Ms. ESHOO. You are recognized for your testimony for 5 minutes. And you are welcome.

STATEMENT OF ANTHONY A. BARRUETA

Mr. BARRUETA. Thank you, Chairman Eshoo, Mr. Burgess, and distinguished committee members. I greatly appreciate the opportunity to testify today.So I am Tony Barrueta, senior vice president for government relations for Kaiser Permanente. As the Nation's largest private integrated healthcare system, we provide care and pharmacy benefits to over 12 million people across the country, dispensing approximately 90 million outpatient prescriptions and over 50 million outpatient and inpatient doses every year.

Our nonprofit model combines coverage and care delivery. We operate pharmacies that dispense drugs prescribed by our Permanente medical group physicians. We, therefore, have a unique perspective on the prescription-drug marketplace and prescription-drug pricing. Our mission for pharmacy, and all the services that we provide, is to deliver high quality, affordable care, and to improve the health of our members and the communities we serve.

We greatly appreciate this committee's attention to the problem of high drug prices. High drug prices impose a crippling burden on our members and our ability to carry out our mission. Drug companies—random drug companies have virtually unfettered discretion to raise prices, which really imposes considerable and often devastating financial hardship on patients and families.

We are very concerned by overpatenting, exclusivity gaming, and pernicious lifecycle management trends. Too often the primary goal of these tactics is to leverage the law to stifle competition, rather than protect meaningful clinical advancements. It is past time for new policy framework that fosters competition and prices that patients and the healthcare system can actually afford, while still rewarding and incenting innovation.

Congress has a critical role to play in mitigating this behavior by evaluating the extent to which the current laws are subject to gaming that empowers the drug companies to extend monopoly pricing well beyond congressional intent.

We applaud the committee for working to make the patent landscape more transparent, curbing REMS abuses, and stopping tactics such as pay-for-delay settlements and exclusivity parking. We are especially grateful that the committee is considering the CREATES Act. These anticompetitive practices significantly delay generic and biosimilar availability, hampering our ability to provide more affordable options for our members. They also create uncertainty that disrupts our ability to design optimal pharmacy benefits.

Our research pharmacists actively monitor drug pipelines to forecast when competition may enter the market. When competition doesn't occur at the expected time, it undermines our efforts to negotiate better prices from drug companies that would allow more affordable premiums and cost-sharing.

Our approach to pharmacy benefit shows what is possible when markets are competitive. We have industry-leading generic utilization, and every one-tenth of one percent increase in our generic utilization saves our system $28 million.

Many in the market have struggled to transition to biosimilars. At Kaiser Permanente, our physicians have embraced them. For example, within our system, Inflectra, the biosimilar, is used over 75 percent of the time instead of Remicade, the reference product. Inflectra utilization in the rest of the market is less than three percent.

Major contributors to our success include our evidence-driven formularies, developed by our physicians and pharmacists, our ability as an integrated system to generate and disseminate unbiassed information about drugs, and our restrictive approach to marketing by pharmaceutical sales representatives in our facilities.

Prescriber confidence is in excellent and unbiassed information, strong investment in clinical support and education, and our physician-pharmacist alignment, are all crucial to facilitating generic and biosimilar uptake. Breaking down barriers for generic entry is of critical importance to our model of care. We simply cannot fully leverage our process to spar competition if generics and biosimilars are not available in the first place. That is why the work of this committee is so important.

We look at these as positive, first steps toward a more functional market for drugs. There are much more to be done. We think other things should be considered, including whether exclusivities on the books now should be narrowed to better balance access and rewarding innovation; whether the FTC should have more expansive authority to review drug companies' anticompetitive practices, including patent abuses; and whether agencies like FDA, NIH, PCORI, AHRQ, and others should play a role in educating through academic detailing and providing unbiased sources of information.

So thank you for considering our perspective on this important set of issues. We share your commitment to lowering drug prices and reducing barriers to biosimilar and generic market entry.

[The prepared statement of Mr. Barrueta follows:]

Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition

Testimony of Anthony A. Barrueta
Senior Vice President, Government Relations
Kaiser Permanente

for the

Committee on Energy & Commerce
Subcommittee on Health
United States House of Representatives

March 13, 2019

KAISER PERMANENTE®

Chairwoman Eshoo, Ranking Member Burgess and distinguished Members of the Committee, thank you for the opportunity to testify today. I am Tony Barrueta, Senior Vice President of Government Relations at Kaiser Permanente.[1] As the largest private, integrated health care system in the United States, we provide pharmacy benefits to over 12 million people, dispensing 90 million prescriptions and administering 54 million inpatient and clinic doses annually. Our non-profit model combines coverage and care delivery. We also operate pharmacies that dispense drugs prescribed by the Permanente Medical Group physicians. Kaiser Permanente therefore has a unique perspective on drug prices. Our mission for pharmacy, and all services we provide, is to deliver high-quality, affordable care and to improve the health of our members and communities we serve.

Kaiser Permanente greatly appreciates the Committee's attention to drug prices. High drug prices impose a crippling burden on our members and our ability to carry out our mission. Drug companies have virtually unfettered discretion to raise prices, which imposes considerable—and often devastating—financial hardship on patients and families. We are very concerned by over-patenting, exclusivity gaming and pernicious lifecycle management trends. Too often, the primary goal of these tactics is to leverage the law to stifle competition, rather than to protect meaningful clinical advancements. It is past time for a new policy framework that fosters competition and prices patients can actually afford, while still rewarding innovation.

Congress has a critical role to play in mitigating this behavior by evaluating the extent to which current laws—including the *Federal Food, Drug, and Cosmetic Act* (FDC Act)—are

[1] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 650 other clinical facilities; and Permanente the Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members. As the largest private integrated health care delivery system in the United States, Kaiser Permanente delivers care to more than 12.2 million members in eight states and the District of Columbia.

subject to gaming that empowers the drug companies to extend monopoly pricing well beyond congressional intent. We applaud the Committee for working to make the patent landscape more transparent and stopping tactics such as pay-for-delay settlements and exclusivity "parking." We are especially grateful the Committee is considering the *CREATES Act*, which would curb abuses of the REMS program that arbitrarily block generic manufacturers from accessing samples they need to conduct the tests required for FDA approval. These anticompetitive practices significantly delay generic and biosimilar availability, hampering our ability to provide more affordable options to our members. They also create uncertainty that disrupts our ability to design optimal pharmacy benefits. Our research pharmacists actively monitor pipelines to forecast when competition may enter the market. When competition does not occur at the expected time, it undermines our efforts to negotiate better prices from drug companies that would allow more affordable premium pricing and cost-sharing.

Our approach to pharmacy benefits shows what is possible when competition exists. Kaiser Permanente has long led the market in generic utilization. The rest of the market has nearly caught up with us, due in large part to greater generic availability across more therapeutic classes. More than 91 percent of drugs prescribed in our system are generic, which exceeds market averages of 89 percent. Every 0.1 percent increase in generic utilization saves our system $28 million. While others have been slow to transition to biosimilars, Kaiser Permanente embraces them. For example, within our system, Inflectra (biosimilar) is used over 75 percent of the time instead of Remicade (the reference biologic). Inflectra utilization in the rest of the market is 2.3 percent. Major contributors to our success include our: (1) evidence-driven formularies; (2) ability as an integrated system to generate and disseminate unbiased information about drugs; and (3) restrictive approach to marketing by pharmaceutical sales representatives.

- Evidence-Driven Formularies: Our approach to designing pharmacy benefits focuses on a drug's clinical value. Permanente Medical Group physicians and Kaiser Permanente research pharmacists collaborate closely to develop our formularies. On an ongoing basis, our pharmacists develop an objective analysis for each drug. Then our physician experts review the evidence and make recommendations. This rigorous approach instills confidence in our formularies, leading our clinicians to prescribe consistently with them in the vast majority of cases. As a result, when generics and biosimilars perform just as well or better than a more expensive brand drug, they prevail within Kaiser Permanente.
- Dissemination of Unbiased Information: Kaiser Permanente generates and disseminates robust clinical information for use at the point of prescribing. "Drug Education Coordinator" pharmacists answer questions and provide information proactively to clinicians. Our integrated structure and use of a common electronic health record (EHR) also enables us to harness real-world data generated within our system to compare effectiveness between drugs and demonstrate that biosimilars are safe and effective. These data provide our clinicians with concrete evidence of positive outcomes, bolstering biosimilar prescribing confidence.
- Restrictions on Pharmaceutical Industry Marketing: The Permanente Medical Groups have policies that significantly restrict marketing or "detailing" by pharmaceutical sales representatives. In general, sales representatives who are allowed in our facilities must register and may not market nonformulary drugs unless specifically asked by a physician. These policies help prevent potentially biased marketing information from deterring prescribers from biosimilars, generics and other high-value therapeutic alternatives.

These best practices enable Kaiser Permanente to deliver pharmacy benefits in a way that thrives on competition and empowers us to negotiate lower prices while delivering positive

outcomes for patients. Breaking down barriers to generic entry is therefore of critical importance to our model of care. We cannot fully leverage our process to spark competition if generics and biosimilars are not available in the first place.

That's why the work the Committee is doing is so important. Today's proposals represent positive first steps toward a more functional and competitive market for drugs, which we know from experience will lead to better, more affordable care. But there is more work to be done. We hope the Committee builds on today's hearing by exploring additional ways to curb pervasive anticompetitive abuses by brand companies. Specifically, we encourage you to consider:

- Whether exclusivities under the *Biologics Price Competition and Innovation Act*, the *Orphan Drug Act* and the *Best Pharmaceuticals for Children Act* could be narrowed to more appropriately balance rewarding innovation with access to affordable medicines;
- Whether the Federal Trade Commission (FTC) should have more expansive authority to review drug companies' anticompetitive practices, including to help Congress understand and address patent abuses, such as patent thickets, evergreening and product hopping; and
- Whether agencies such as Food and Drug Administration (FDA), the National Institutes for Health (NIH), the Patient-Centered Outcomes Research Institute (PCORI), the Agency for Healthcare Research and Quality (AHRQ) and others could play a role in providing academic detailing and unbiased sources of information to counter drug company marketing tactics such as direct-to-consumer (DTC) advertisements, industry detailing and free samples.

Thank you for considering our perspectives on these important issues. Kaiser Permanente shares your commitment to lowering drug prices and reducing barriers to biosimilar and generic market entry. We look forward to working with you to advance meaningful solutions.

Ms. ESHOO. And look at that, you just stayed right within your 5 minutes. Excellent. Thank you very, very much.

I now would like to recognize Mr. Boutin, the chief executive officer of the National Health Council. Welcome, and you have 5 minutes for your oral testimony.

STATEMENT OF MARC M. BOUTIN

Mr. BOUTIN. Good morning, Chairwoman Eshoo, Chairman, Ranking Member Burgess, and members of the Subcommittee on Health.

Bad actors have gamed the system, driving up costs for patients, and only Congress can fix it. My name is Marc Boutin. I am the CEO of the National Health Council. I became a patient advocate more than 20 years ago, when virtually every member of my family was diagnosed with one or more chronic conditions, ranging from cancer, heart disease, neurological, autoimmune, an ultra-rare condition, and HIV.

I sat in the doctor's office with my parents, when my father was told he had a terminal cancer. As a result of the treatments he underwent, he lost the dexterity in his fingers. The challenge was, he had an antique clock business. So he also lost the income for the family. Like so many people with chronic conditions, healthcare costs pile up. My sisters and I moved my mother to a smaller, more affordable home after his death. She died of a heart attack before all the boxes were unpacked.

The impact of medical debt on the financial, emotional, and clinical well-being of more than 160 million people living with one or more chronic conditions has become a national crisis. The National Health Council is a nonprofit organization that was created by and for patient advocacy organizations.

While the patient groups control our governance, and our policymaking process, we welcome all stakeholders into membership. We have the biopharmaceutical companies, the device diagnostic, generics, payer, provider, researcher, and family caregiving communities all represented in membership.

Over the last few years, we have heard loud and clear from our members that while patients care deeply about getting better and new treatments, they are having incredible challenges affording the medications that they need. According to a recent poll, 49 percent of people in poor health, the people we represent, are having significant challenges getting their medications.

Young, expecting families used to tell us their greatest fear was having a child with a deadly disease and no effective treatment. What they tell us now is, their fear is having a child with a deadly disease for which there is a treatment, but they cannot afford it.

The National Health Council reviewed nearly 200 policy proposals all aimed at reducing healthcare costs. We learned two things: One, the vast majority of those policies actually reduced costs by eliminating access. And for the remaining policies, there was virtually no data to show that they would actually drive down costs. With one major exception. And that is increased competition, especially among generics. On this point, the data is unequivocal and so are the experiences of millions of Americans.

Mackenzie is a 32-year-old, running her own business in North Carolina. She has a common, genetic condition called familial hypercholesterolemia. She was born with cholesterol levels more than three times the level normal, putting her at extreme risk of an early heart attack. Adding Zetia, a brand product, to her statin regimen had the potential to greatly improve her cholesterol level. But the cost was an additional $60 a month on top of all her other medical expenses, a huge burden for a young professional just starting off in her own business. When the medicine went generic, her cost dropped to $5 a month.

We, in the patient community, keenly understand the need for intellectual property and exclusivities to drive innovation, but when bad actors abuse the current system to delay access to generics and biosimilars, people with chronic conditions and their family caregivers suffer. Congress needs to address this.

While some patent settlements can bring generics to market quicker, far too many delay entry and line the pockets of investors at the expense of patients. Similarly, without REMS, many people would not have access to medications to improve how they feel, function, and survive. When bad actors use REMS to block generics and biosimilars to markets, we have a serious problem.

We recognize this is a complex issue, but I want to tell you, this is a great first step. On behalf of Mackenzie, my family, more than 160 million people with chronic conditions and their family caregivers, thank you.

[The prepared statement of Mr. Boutin follows:]

Testimony of Marc M. Boutin, JD
Chief Executive Officer
National Health Council

Hearing on "Lowering the Cost of Prescription Drugs:
Reducing Barriers to Market Competition"
March 13, 2019

United States House of Representatives
Committee on Energy and Commerce Subcommittee on Health

Good morning Chairwoman Eshoo, Ranking Member Burgess, and distinguished members of the Subcommittee on Health. My name is Marc Boutin, and I serve as the Chief Executive Officer of the National Health Council (NHC).

I am honored to join the Subcommittee today to discuss the importance of a thriving generics and biosimilars market to promote competition to drive down costs and increase access for people with chronic diseases and disabilities. I am also here today to talk about specific anti-competitive practices that are causing a chilling effect on robust competition.

Background on the National Health Council

Founded in 1920, the NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 160 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 125 diverse national health-related organizations and businesses[1], the NHC's core membership includes the nation's leading patient advocacy organizations. Other dues-paying members include professional and membership associations; nonprofit organizations with an interest in health; representatives from the pharmaceutical, generic drug, health insurance, device, and biotechnology industries; and research, provider, and family caregiving organizations. Because of this diverse membership, the NHC can harness the collective expertise of the broader health community to address systemic issues that affect access to affordable, high-quality care for all patients, regardless of disease or disability. At the same time, while all NHC members are provided the opportunity to provide input into our public policy and education initiatives, control over the NHC's governance and policy-making process resides with our core membership of patient advocacy organizations.

In addition to membership dues payments, the NHC receives financial sponsorships[2] for programmatic activities from biopharmaceutical, generic drug, device, and insurance companies, and their trade associations. The NHC and our member patient organizations meet

[1] https://www.nationalhealthcouncil.org/about-nhc/membership-directory
[2] https://www.nationalhealthcouncil.org/about-nhc/sponsors

our Standards of Excellence®[3] requirements to ensure our work is transparent, independent, and mission-driven.

Rising health care costs create significant challenges for the patient community.

Over the last few years, I have conducted numerous listening sessions with CEOs of patient organizations, asking them to describe the most significant challenges their constituents currently face. According to a recent poll by *Kaiser Health News*, almost half of people in poor health – our constituents – have a hard time paying for their medications.[4] While patient organizations care deeply about driving innovation to help their constituents improve how they feel, function, and survive, they are equally or more concerned about affordable access to high-value care. Even people with life-threatening conditions such as certain types of cancer, neurological, and rare diseases are finding significant access barriers to routine care, and those with historically inexpensive, yet effective, treatments like heart disease have found their costs rising dramatically.

Take for example the story of Mackenzie.

Mackenzie is a 32-year-old writer from North Carolina running her own small business. She has the common genetic condition called Familial Hypercholesterolemia (FH). She was born with cholesterol levels more than three times normal, putting her at very high risk for an early heart attack. FH caused her mother to have quadruple bypass at age 42, so Mackenzie works hard to keep her own cholesterol low. FH management requires medication, often with more than just a statin.

Mackenzie knew adding another medication, Zetia, to her statin treatment would help get her cholesterol closer to normal. She struggled with whether she could afford it on top of her existing medical bills. Mackenzie ended up paying $60 out-of-pocket per month for Zetia on top of her other medicines - a real burden for a young professional just starting out. When the generic version – ezetimibe – became available at the end of 2016, the cost dropped to $5 a month. Being able to afford the medication improved her health and reduced her stress, a pivotal factor in heart disease prevention.

Every day, people across the country are forced to make the difficult decision about filling their prescriptions, paying rent, or putting food on their tables. For the more than 160 million people in the US who live with a chronic disease or disability, we must do better. Reducing barriers to market competition is a much-needed step to reducing health care costs for people like

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[3] The NHC has adopted a set of good operating practices to ensure that its member patient organizations maintain the highest standards of organizational effectiveness and public stewardship. To become a member of the NHC, patient advocacy organizations must meet the requirements set forth in the NHC's Standards of Excellence Certification Program®, which includes 38 standards covering the areas of governance, human resources, programs, fundraising, finance, accounting and reporting, and evaluation. Notably, these standards include requirements that any financial relationships with pharmaceutical manufacturers to be publicly reported, independent, and directed toward a mission-related benefit. http://www.nationalhealthcouncil.org/resources/standards-excellence-certification-program.

[4] Kirzinger, A, et al. KFF Health Tracking Poll – February 2019: Prescription Drugs. March 1, 2019

MacKenzie. However, this is just one component of a broader strategy to reduce health care costs, including, but not limited to, drug spending.

Increasing the availability of generic drugs and biosimilars reduces costs for patients.

In the fall of 2016, the NHC evaluated nearly 200 policy proposals that aim to reduce the cost of health care. Based on that evaluation, we put forward a number of potential solutions we believe can help reduce health care costs, including drug prices, without limiting access, sacrificing quality, or hindering innovation.[5] Unfortunately, the vast majority of proposals that purport to reduce costs do so at the expense of access to care for those most in need.

More importantly, we also found that very few proposals are actually supported by evidence demonstrating they will in fact reduce costs. The one major exception is increasing competition, especially through generic-drug competition. Studies, including an analysis by the U.S. Food & Drug Administration (FDA), show that having multiple generic drugs on the market dramatically lowers drug prices.[6,7] Thus, it is imperative that we focus on policies that lead to greater availability and utilization of generics and biosimilars, as long as these policies consider clinical nuances to ensure people have access to the most appropriate treatments.[8]

In fiscal year 2018, due in-part to NHC-supported provisions included in the FDA Reauthorization Act, a record 1,021 generic drugs were approved or tentatively approved by FDA.[9] To ensure this trend continues, the NHC has supported FDA's efforts to reduce barriers to generic-drug approval. Additionally, we support proposed regulations being considered by the Administration to ensure patients are aware of the availability of generic drugs and lower-cost alternatives in public programs and encourage further action related to formulary transparency.

The NHC sees similar opportunities with biosimilars. While biologics provide tremendous value to patients, lack of competition in the marketplace has contributed to high prices for patients. Approximately 1-2% of the population use biologics, yet they account for nearly 40% of

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[5] National Health Council. NHC Policy Proposals for Reducing Health Care Costs. 2017. http://www.nationalhealthcouncil.org/healthcarecosts.

[6] U.S. Food & Drug Administration. Generic Competition and Drug Prices. 2017. https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm

[7] Alpern JD, et al. Trends in Pricing and Generic Competition Within the Oral Antibiotic Drug Market in the United States. Clin Infect Dis. 2017 Nov.

[8] For the vast majority of patients, generics work just as well as branded drugs. However, some patient populations have high levels of heterogeneity, resulting in instances where slight changes to formulations can have significant impacts on effectiveness and side effects. Similarly, while some biosimilars in certain disease states can be considered "interchangeable," switching in other disease states can have devastating consequences. Thus, it is important to consider safeguards to allow individuals to access branded treatments if they are more medically appropriate than a generic or biosimilar.

[9] U.S. Food & Drug Administration. Office of Generic Drugs. 2018 Annual Report. 2018. https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM631997.pdf

prescription drug spending.[10] A robust biosimilars market has the potential to reduce costs in our health care system and improve access and affordability for millions of patients. The NHC supports policy measures that encourage the development and adoption of biosimilar therapies, including recent steps taken by the FDA to improve the efficiency of the biosimilar approval process and to clarify development and approval requirements.

Anti-competitive business practices are preventing generic and biosimilar entry.

The NHC keenly understands the need for intellectual property protections to drive innovation. Patents and FDA exclusivities reduce uncertainty for biopharmaceutical companies and investors. They provide incentives for companies to invest in research and development to bring lifesaving medicines to millions of patients who do not have effective treatments or cures. However, some companies have abused these laws.

I highlight two practices limiting the market entry of generic drugs and undermining the intent of current laws and regulations: First is the use of patent settlements (also called for "pay-for-delay" settlements) to prevent timely entry of generics and biosimilars into the market. Second is the use of the FDA's Risk Evaluation and Mitigation Strategies (REMS) program to prevent generic manufacturers from acquiring needed reference materials to conduct testing necessary to secure FDA approval.

Pay-for-Delay Settlements
Patent settlements between brand and generic drug manufacturers may sometimes delay the entry of generics beyond when they would normally come onto the market. While there are instances where patent settlements between brand and generic manufacturers can reduce the cost of litigation and bring generics onto the market sooner, there are also instances in which the settlements are intended simply to block the entry of a generic drug to the market (those "pay-for-delay" settlements).

Use of REMS to Delay Market Entry
For drugs with known or potential risks, REMS is an important program that protects patient safety. However, the REMS program has been exploited by some brand manufacturers to block generic- and biosimilar-product developers from accessing sufficient doses of a brand product needed to conduct studies required for FDA approval of a new generic or biosimilar. The FDA has received more than 150 requests from generic drug developers seeking assistance in obtaining samples from brand companies, so many that the FDA has taken to making a list of these inquiries public.[11]

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[10] Rand Corporation. Biosimilar Cost Savings in the United States. 2017. https://www.rand.org/content/dam/rand/pubs/perspectives/PE200/PE264/RAND_PE264.pdf
[11] U.S. Food & Drug Administration. Reference Listed Drug (RLD) Access Inquiries. Updated February 7, 2019. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm.

A related issue occurs when brand and generic drug manufactures must share a single REMS program. In this scenario, a generic drug manufacturer must reach an agreement with a brand manufacturer on a shared REMS program. According to the FDA, these negotiations may be used strategically by brand manufacturers to delay the market entry of a generic drug.[12]

These practices – and other techniques that delay generic and biosimilar entry – must be addressed by Congress. They prevent the potential cost-savings that can be achieved through the competition of multiple generics on the market. The end result is that people pay more at the pharmacy counter, preventing many of them from accessing meaningful care.

Other market forces are also limiting competition.

Unfortunately, the tremendous recent increase in generic approvals have not always resulted in increased access. A recent report by the Kaiser Family Foundation found that 43% of generic drugs—about 700—approved by the FDA since January 2017 are still not on the market.[13] The report notes that part of the reason for this is the type of anti-competitive practices that we are discussing today. However, they also note other factors such as industry consolidation and business decisions not to manufacture specific products have resulted in many of the approved generics never making it to market.

While outside of the scope of today's hearing, Congress and the Administration must work to address significant misalignment of incentives and lack of transparency throughout the drug distribution system. As noted by FDA Commissioner Scott Gottlieb, when insurers and pharmaceutical benefit managers have greater incentive to include branded drugs and biologics on their formularies than generics and biosimilars[14], we risk missing out on the promised cost savings generics and biosimilars could provide to the millions of people with chronic conditions who desperately need them.

Conclusion

We commend the Health Subcommittee for shining a light on some of the practices that limit patient access to affordable medicines. We and our members stand ready to work with Congress on policies to reduce the costs of medicines. It is important we work together on policies that achieve cost reduction but not at the expense of access to effective medications. Such approaches often result in worse outcomes and increased costs for hospital, emergency

[12] U.S. Food & Drug Administration. Statement from FDA Commissioner Scott Gottlieb, M.D. on new steps to improve FDA review of shared Risk Evaluation and Mitigation Strategies to improve generic drug access. November 8, 2017.
https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm584259.htm
[13] Lupkin, S and Hancock, J. Trump Administration Salutes Parade of Generic Approvals, but Hundreds Aren't for Sale, Kaiser Health News. February 7, 2019.
[14] https://www.fda.gov/newsevents/speeches/ucm599833.htm

department, or other health care services.[15] Thus, a holistic approach that looks at total costs of care is needed.

Increasing competition in the drug market is an important step in the nation's effort to lower health care costs to increase patients' access to needed treatment. But, it should not be the only step. We call upon Congress to consider all the drivers of health care costs and craft holistic policies that can reduce the significant financial burden on people with chronic diseases and disabilities and their family caregivers.

Thank you for the opportunity to speak with you today and for joining us in making increasing access to affordable, sustainable, high-value health care a national priority. I look forward to working with you and welcome any questions you may have.

[15] Hsu J., et al. Unintended Consequences of Caps on Medicare Drug Benefits. N Engl J Med. 2006

Ms. ESHOO. Thank you, Mr. Boutin. Powerful testimony.

Now, I would like to recognize Mr. Karst. He is the director at Hyman, Phelps & McNamara. Welcome to you, and you have 5 minutes for your oral testimony.

STATEMENT OF KURT R. KARST

Mr. KARST. Thank you. Good morning, Chairwoman Eshoo, Ranking Member Burgess, and distinguished members of the Subcommittee on Health. My name is Kurt Karst. I am a director at the law firm of Hyman, Phelps & McNamara, where I specialize in food and drug law and, in particular, the Hatch-Waxman amendments—and I say that as I look up at Chairman Waxman's portrait—and the Biosimilars Act. I am a coauthor of the legal treatise Generic and Innovator Drugs: A Guide to FDA Approval Requirements, and a cofounder of the popular FDA Law Blog.

I am honored to participate in today's hearings and would like to make clear at the outset that I am testifying today in my personal capacity and that the views I express are solely my own and not the views of my law firm or any company or client of my firm.

The information and perspectives I provide today are based on nearly 20 years of experience, helping drug and biologic manufacturers, both on the brand and on the generic side, in helping them obtain approval of life-saving therapies.

So first, do no harm. It is a maxim as old as medicine itself, and it is one of the principal precepts of medicine and bioethics, and I believe it applies to the law just as much as it does to medicine. As an attorney who studies and cares deeply for the Hatch-Waxman amendments, I am always concerned about what good or what harm proposals to amend these laws might cause, or if they are needed at all. In my experience, amending and tinkering with the Hatch-Waxman amendments is akin to performing brain surgery. One wrong move can have dire consequences. So it is through this first do-no-harm lens that I approach the package of bills at issue in today's hearing.

Now, we obviously don't have time to get into all the nitty-gritty for each of the bills. I place them into three buckets: First, those addressing drug and biologic product information transparency; those involving 180-day exclusivity and patent-settlement agreements; and third, those seeking to facilitate generic manufacturers' access to brand-name products.

In the first bucket, we have H.R. 1503, the Orange Book Transparency Act, and H.R. 1520, the Purple Book Continuity Act. H.R. 1503 seeks to clean up and, to some extent, modernize the Orange Book, a publication of approved prescription and over-the-counter products which I brought an example of here today.

The Orange Book is really the linchpin of the Hatch-Waxman amendments and the generic drug approval process. Generic drug manufacturers depend on it to list accurate patent and exclusivity information as they consider what generic drugs to develop.

H.R. 1503 authorizes FDA to remove from the Orange Book information on patents determined to be invalid, to allow the listing of unspecified, additional patent information and to prohibit the listing of information on drug-delivery devices. Broadening or narrowing the scope of information on patents that can be included in

the Orange Book could dramatically impact the timing of generic market entry.

H.R. 1520 would require FDA to include in the Purple Book, which are two lists published by FDA of licensed biological products, certain patent information on brand-name reference products, but this information would only be added after the initiation of the patent litigation provisions of the statute instead of immediately after licensure of a brand-name product.

While the proposed patent information provisions in the bill are, in my opinion, a good first step to facilitating biosimilar availability, Congress should consider whether an enhanced patent notice feature should be added to the law.

Moving on to the second bucket, we have the BLOCKING Act, the FAIR Generics Act, and then the Protecting Consumer Access to Generic Drugs Act. So 180-day market exclusivity for the first generic drug manufacturer that risks patent infringement litigation, incentivizes companies to clear the patent thicket. Today in a highly competitive, generic drug market, where only a handful of manufacturers may be able to successfully commercialize a drug, exclusivity is the brass ring. Legislative measures that dilute or obscure that prize could jeopardize the generic drug industry, and, in fact, the BLOCKING Act would do just that.

It seeks to prevent exclusivity-eligible applicants from parking their exclusivity when alleged deficiencies prevent FDA from granting final ANDA approval, when subsequent ANDA applicants otherwise eligible for approval are ready. Whatever merit that proposal may have, the BLOCKING Act would address it by imposing immensely and unnecessarily complex framework to trigger 180-day exclusivity, and the analysis under that framework becomes more complex with the addition of each variable.

As a food and drug lawyer, this proposal will certainly keep me in business for a generation, but few others will benefit from the costly and time-consuming litigation these changes will spur. The generic industry won't. This bill will make the 180-day exclusivity eligibility far more unpredictable. In my opinion, the BLOCKING Act is unnecessary, and, in fact, FDA already has a statutory and regulatory authority to deal with this situation.

Both H.R. 1506 and 1499 address patent-settlement agreements peppered with a dash of exclusivity. From my standpoint, patent-settlement agreements are generally procompetitive and represent a fair balancing of the parties' relative risks from inherently uncertain litigation.

And, finally, the CREATES Act and the FAST Generics Act, both these bills would go a long way to address, I believe, legitimate concerns about reference product access.

[The prepared statement of Mr. Karst follows:]

Testimony of Kurt R. Karst
Director
Hyman, Phelps & McNamara, P.C.
Washington, D.C.

Hearing on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"

United States House of Representatives
Committee on Energy and Commerce Subcommittee on Health
March 13, 2019

Good morning Chairwoman Eshoo, Ranking Member Burgess, and distinguished members of the Subcommittee on Health. My name is Kurt R. Karst. I am a Director at Hyman, Phelps & McNamara, P.C, where I specialize in food and drug law, and, in particular, the Drug Price Competition and Patent Term Restoration Act of 1984 (or "Hatch-Waxman Amendments"), and the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA" or "Biosimilars Act"). I am also a co-author of the legal treatise *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*, and a co-founder of the popular FDA Law Blog (www.fdalawblog.net). I am honored to participate in today's hearing. I would like to make clear at the outset that I am testifying today in my personal capacity and that the views I express are solely my own and not my law firm's or any company or client of my law firm.

The Subcommittee has asked for my views regarding several bills that are intended to lower the cost of prescription drugs and biologics. The information and perspectives I provide today are based on nearly twenty years of experience helping drug and biologic manufacturers—both brand-name and generic drug manufacturers—obtain FDA approval for life-saving therapies and high quality, low-cost generic versions of drug and biological products.

"First, do no harm"—or "primum non nocere" in Latin—is a maxim as old as medicine itself. It is one of the principal precepts of medicine and bioethics. And I believe it applies to the law just as much as it does to medicine.

As an attorney who studies and cares deeply for the Hatch-Waxman Amendments—and some might say obsessively so, particularly when it comes to FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, or the "Orange Book", which I carry with me as I travel the world—I always am concerned about what good or what harm proposals to amend these laws might cause—or if they are needed at all. In my experience, amending and tinkering with the Hatch-Waxman Amendments is akin to performing brain surgery: one wrong move can have dire consequences. So it is

through the "first, do no harm" lens that I approach the package of bills at issue in today's hearing.

We obviously do not have time to cover the details of each of the seven bills on today's agenda, but I do have particular comments on some of the bills. To help simplify things, these bills can be roughly sorted into three "buckets": (1) those addressing drug and biological product information transparency; (2) those involving 180-day generic drug exclusivity and patent settlement agreements; and (3) those seeking to facilitate generic manufacturers' access to the brand-name samples needed to participate in the Hatch-Waxman and biosimilar processes.

Drug and Biologic Information Transparency

- ***H.R. 1503 – "Orange Book Transparency Act of 2019"***

H.R. 1503, the "Orange Book Transparency Act of 2019," seeks to clean up—and to some extent, modernize—the Orange Book, a publication of approved prescription and over-the-counter drug products, including patent and regulatory exclusivity information, that has been around for nearly 40 years. The Orange Book is the linchpin of the Hatch-Waxman Amendments and the generic drug approval process. Generic drug manufacturers depend on it to list accurate patent and exclusivity information as they consider what generic drugs to develop. And including—or excluding—patent information in the Orange Book can have a significant effect on the timing of generic drug approval.

H.R. 1503 authorizes FDA to remove from the Orange Book information on patents determined to be invalid, to allow the listing of unspecified "additional patent information," and to prohibit the listing of information on drug-delivery devices. These changes could dramatically impact the timing of generic market entry. To cite just one example, the Hatch-Waxman Amendments typically prevent FDA from approving a generic version of a previously approved drug for 30 months if the innovator files a patent infringement lawsuit on a patent that's listed in the Orange Book. Broadening or narrowing the scope of information on patents that can be included in the Orange Book can therefore affect the timing of generic drug approval.

H.R. 1503 also would give FDA the authority to "choose to include [in the Orange Book] additional patent information respecting the drug." It is unclear, however, what is meant by "additional patent information." To the extent that information on patents other than drug substance, drug product, and method-of-use patents could be included in the Orange Book, the Orange Book patent thicket could become all that thicker for generic drug manufacturers to go through. But to the extent such "additional patent information" means greater information on listed patents purported to cover an approved drug

substance, drug product, or method-of-use, such information could be helpful to generic drug manufacturers. Additional clarity is needed on this point.

- ***H.R. 1520 – "Purple Book Continuity Act of 2019"***

If the Hatch-Waxman Amendments are the marriage between food and drug law and patent law, then the Biosimilar Act is the divorce between them. With more than 25 years of experience with Hatch-Waxman under its belt, Congress decided with the passage of the Biosimilars Act to separate biosimilar licensure from patent infringement proceedings. Whether or not this was a good decision is an issue up for debate.

While the Orange Book is the linchpin to the Hatch-Waxman Amendments, the *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*—otherwise known as the "Purple Book"—is merely ancillary to the Biosimilars Act and is not currently mandated by statute. H.R. 1520 would change that by requiring FDA to publish the Purple Book and to update it each month.

H.R. 1520 would also require FDA to include in the Purple Book certain patent information on brand-name reference products. But this information would only be added after initiation of the so-called "patent dance" provisions of the statute instead of immediately after licensure of the brand-name product. While the proposed patent information provision of H.R. 1520 is, in my opinion, a good first step to facilitating biosimilar availability, Congress should consider whether a more enhanced patent notice feature should be added to the law.

180-Day Generic Drug Exclusivity and Patent Settlement Agreements

- ***H.R. 938 – "Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2019" or the "BLOCKING Act of 2019"***

The 180-day marketing exclusivity period for the first generic drug manufacturer that risks patent infringement litigation incentivizes companies to clear the patent thicket. Today, in a highly competitive generic drug market where only a handful of manufacturers may be able to successfully commercialize a drug, 180-day exclusivity is the brass ring. Legislative measures that dilute or obscure that prize could jeopardize the generic drug industry. The BLOCKING Act would do just that.

The bill seeks to prevent exclusivity-eligible applicants from "parking" their 180-day exclusivity when alleged deficiencies prevent FDA from granting final ANDA approval when subsequent ANDA applicants otherwise are ready for approval. Whatever merit that proposal has, the BLOCKING Act would address it by imposing an immensely and unnecessarily complex framework to trigger 180-day exclusivity—and the analysis

under that framework becomes more complex with the addition of each variable (e.g., multiple first applicants).

As a food and drug lawyer, this proposal will keep me in business for a generation. Few others will benefit from the costly and time-consuming litigation these changes will spur. The generic industry certainly won't: This bill will make 180-day exclusivity eligibility far more unpredictable for ANDA applicants, reducing the incentives generics have to challenge brand manufacturers' patents. And it would be difficult to apply in practice: Information on some of the factors that can lead to the triggering of exclusivity under the BLOCKING Act is not readily available (or is not immediately available) to the public, such as the time of a subsequent applicant's tentative approval and the date of submission of an ANDA.

In my opinion, the BLOCKING Act is not necessary. Indeed, FDA already has the statutory and regulatory authority to determine that eligibility for 180-day exclusivity is forfeited or that exclusivity should not be granted because a first applicant has not diligently pursued ANDA approval.

- ***H.R. 1506 – "Fair and Immediate Release of Generic Drugs Act" or the "FAIR Generics Act of 2019"; and H.R. 1499 – "Protecting Consumer Access to Generic Drugs Act of 2019"***

Both H.R. 1506 and H.R. 1499 address patent settlement agreements—or so-called "pay-for-delay" agreements—peppered with a dash of 180-day exclusivity. Although I am not a patent attorney, from my standpoint as a Hatch-Waxman attorney, legislation that bans or severely restricts patent settlement agreements can delay generic competition and lead unnecessarily to time-consuming and costly patent infringement litigation. That is, from my standpoint, patent settlement agreements are generally pro-competitive and represent a fair balancing of the parties' relative risks from inherently uncertain litigation. Legislation that also brings 180-day exclusivity into the mix is doubly concerning as it dilutes the value of and brings greater uncertainty to that statutory incentive.

Reference Product Access

- ***H.R. 965 – "Creating and Restoring Equal Access to Equivalent Samples Act of 2019" or the "CREATES Act of 2019"; and H.R. 985 – "Fair Access for Safe and Timely Generics Act of 2019" or the "FAST Generics Act of 2019"; and***

H.R. 965 and H.R. 985 both address the availability of reference product sample needed for comparative testing and the eventual submission of a marketing application for a generic drug or biosimilar biological product. This topic has received increased attention in recent years. Indeed, last May, FDA Commissioner Scott Gottlieb announced that the Agency started publishing a list of reference product access inquiries

to provide transparency to the general public about this potential impediment to competition.

Both H.R. 965 and H.R. 985 would address the sample access concern, as well as other Risk Evaluation and Mitigation Strategies issues, to establish a system that more effectively facilitates generic competition. The bills would go a long way to address legitimate concerns about reference product access.

Again, I would like to thank the Subcommittee for inviting me to testify on this set of legislative proposals. I look forward to working with you and your staff and welcome any questions you may have.

Kurt R. Karst,
Director
Hyman, Phelps & McNamara, P.C.

Ms. ESHOO. Thank you very much.

Now I have the pleasure of recognizing Mr. Kushan.

Mr. KUSHAN. Kushan, yes.

Ms. ESHOO [continuing]. Kushan. He is a partner at Sidley Austin, and I am pleased to recognize you for your oral testimony for 5 minutes.

STATEMENT OF JEFFREY P. KUSHAN

Mr. KUSHAN. Thank you, Madam Chairwoman, and thank you to the members of the committee, to Ranking Member Burgess for giving me this opportunity to offer some remarks today. I am a private attorney. My comments today are my personal views, and they should not be attributed to any client of our firm.

I provided some general observations on innovation and the way that things work in the innovative side of the industry, and I would like to just address a few additional issues.

Before I do that, it is important for the subcommittee to appreciate the nature of innovation in this industry. Every life sciences company that I have had an opportunity to work with in my career has the same goal. They want to make the best new medicines to help patients. That is what is driving these companies to work every day.

They obviously start with the big bang, they come up with a new idea that leads to a new drug, a new therapy, but they don't stop innovating at that point, they keep innovating. They have to innovate as they develop the way to make this drug in large scale and in a way that is going to be safe and can be delivered to the patients.

They also don't stop innovating when they get FDA approval of their drugs. They keep innovating because they want to make their drugs better. They want to make better manufacturing processes. They want to develop new ways of making the drugs easier to use by patients. And all these things that they are developing are aimed at making better products that improve the lives of the patients.

And as you go through that process, as an innovator, you look for opportunities to deliver these things to the market. At the very beginning of the biotech industry, there were a number of drugs that came out, that had to be administered through injections, and you had to go into a hospital or outpatient center. Innovations after approval led to development of pen devices and other ways of getting those products into the patient safely where they could administer them in their home.

There are innumerable benefits that come from this continued process of innovation in the industry, and we don't want to do anything that is going to discourage these companies from stopping that innovative instinct they have, both before and after the initial approval of a drug.

Now, I have got a few observations on some of the bills that have been presented. First, I would like to talk about the patent listing ideas that have been proposed for biologics. This is H.R. 1520. One thing I think we need to clarify is that biotechnology companies, whether they are in the innovative or biosimilar side of the process,

have no difficulty finding patents that are relative to what they are doing.

Patents are public. They are put into databases. We use sophisticated tools. I do this myself to find patents that are relevant to the technologies that are being used to make the products. These companies are also very large and sophisticated. They are going to make a significant investment in building factories or reconfiguring them to make biosimilars. There is not a problem in finding patents that are relevant.

I think the other thing that it is important to appreciate about the design of the BPCIA is that it does not slow down the approval of a biosimilar based on whether there is patent litigation. The FDA approves those applications as they are submitted. There is no impact like in the Hatch-Waxman scheme, where there is a listed patent.

So at the end of the day, if a biosimilar has received approval for their product, they can launch. When they don't launch, they typically are looking at a patent they recognize as valid and will cause consequences if it is infringed. It is important to appreciate that variable in the equation, because what that is showing you, is that the incentive of the patent system is working. It is protecting the innovation that merited a patent, and it is driving conscious business decisions of these companies to not launch and risk infringement of that valid patent.

The third thing to keep in mind is that the innovators can't find the patents that are relevant to a particular biosimilar applicant because those are going to depend on information only the biosimilar applicant has. It is their manufacturing information.

I raise one practical concern that in the bill that was proposed, that there is a requirement for the innovator to immediately provide information to the FDA about which patents are implicated by the biosimilar's manufacturing process. As someone who is subject to protective orders, I am a little bit skittish about doing that before there is a public disclosure of the patent litigation, because that means you may be implicating the confidential information of the biosimilar.

The other thing I would like to flag, just very briefly, is the Orange Book Transparency Bill, and that is H.R. 1503. And this raises a question about which patents may no longer be put into the Orange Book. Particularly, they are excluding medical device patents, and many of these technologies are used to make the drug effective. I think we want those patents to be part of the system of early notice and patent resolution, so they don't disrupt the later launch of the products after they are on the market.

I am happy to take any further questions the committee may have.

[The prepared statement of Mr. Kushan follows:]

Testimony of

Jeffrey P. Kushan

Before the
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives
Congress of the United States

Hearing on "Lowering the Cost of Prescription Drugs:
Reducing Barriers to Market Competition"

Chairwoman Eshoo and distinguished members of the Subcommittee:

Thank you for providing me with the opportunity of testifying before you today. I am testifying in my individual capacity based on my personal experiences with patent litigation in the life sciences sector. The opinions I offer in this testimony are my own and should not be attributed to any client of my firm.

I am a patent lawyer who has represented developers of new drugs and new biological products in patent litigation under both the Hatch-Waxman Act and under the Biologics Price Competition and Innovation Act (BPCIA). I also have defended life sciences and non-life sciences companies in litigation where patents have been asserted against them. And I have both challenged and defended patents in *inter partes* review proceedings before the Patent Trial and Appeal Board at the Patent Office.

Before entering private practice in 1998, I worked in the government for about ten years. I served in the Patent and Trademark Office as a biotechnology patent examiner, and later as an attorney on patent policy matters. I also served for two years in the Office of the United States Trade Representative in Geneva, where I gained an appreciation for the different ways our trading partners manage their patent systems and regulation drugs and biologics.

I believe my varied experiences have given me a good sense of the balance built into the patent system, and in the practical considerations that companies face in navigating patent disputes involving regulated products like drugs and biologics. From

these experiences, I can make the following observations that are relevant to many of the bills the subcommittee is now considering.

First, the unpredictable and burdensome nature of patent litigation encourages parties to find ways to resolve patent disputes through settlements. It is very difficult for both patent owners and those accused of infringement to predict with certainty whether a court will find a patent valid and infringed, and what the consequences of infringement will be. Litigation is also very disruptive for companies—the parties must make employees available for depositions and trial, and place demands on their time to help with discovery. And the outcomes of litigation, of course, can be very disruptive on the commercial activities of both parties—they can disrupt expectations, and force significant changes in the commercial operations of the company.

This is why, in my experience, regardless of the technology at issue, both sides of a patent dispute—the patent owner and the party accused of infringement—have a strong interest in finding a way to settle the patent litigation early in the dispute, even while they are aggressively litigating. Settlements often are the only practical way to secure the certainty companies need to plan and conduct their commercial operations and to avoid the disruptions that occur during litigation.

The parties to a patent dispute also are not the only entities with a strong interest in settling patent disputes. Courts have a very strong interest in seeing cases settle. Patent cases can be very demanding for a district court judge. They are technically complex, which makes resolving discovery disputes difficult. There are numerous hearings that take place during a typical patent case—on claim construction and dispositive motions. And trials take substantial time and effort for the Court to conduct and manage. Courts, thus, strongly encourage settlement of patent disputes.

Consequently, measures which effectively foreclose the possibility of settling patent litigation once it has started need to be considered very carefully. This is particularly true for litigation under the Hatch-Waxman Act and the BPCIA, where settlements can facilitate market entry of a generic or biosimilar product earlier than would be possible if the litigation continues to completion, and the relevant patents are

found both valid and infringed. In those situations, market entry by the biosimilar or generic product cannot occur until expiration of the valid and infringed patents.

Second, objectivity, clarity and certainty in the rules that govern patent enforcement and market entry for generic and biosimilar products are critical for both innovators and generic/biosmilar manufacturers. Innovators typically start development of a new drug or biologic a decade or more before the drug or biologic will be approved for use in patients. Companies must make substantial investments to clinically test these new drugs and biologics in the back third of this development period, and those business decisions are influenced by amount of certainty or uncertainty that exists about when a generic or biosimilar version of the new product they are developing will be marketed. Biosimilar and generic manufacturers also need certainty to plan their investments and activities. This is particularly true for biosimilar developers, who must make substantial investments in developing manufacturing facilities that are needed to produce biological products. Uncertainty over how the rules work, whether patents can be effectively enforced and whether the rules will change after investments have been made will have negative systemic effects on the environment for investments in clinical development of original and subsequent versions of drugs and biological products.

Third, it is critically important for the ultimate beneficiary of innovation in the life sciences sector—the patient with unmet medical needs—that we maintain the strong incentives for innovation that the patent system provides. Innovation is not limited to the discovery of a new active ingredient or a new therapeutic use of a known drug. Innovation is pervasive, incremental and occurring within all participants in the life sciences industry. For example, biosimilar manufacturers are innovating—they are discovering—and patenting—new ways to manufacture biological products, new characterization technologies used to achieve consistent quality in production of their products, and new ways of formulating these products to make them safe and to exhibit improved characteristics. These patented innovations track the innovation experience of the original developers of the biological product—the process of starting with a protein and figuring out how to manufacture it at a large scale, and to then formulate it so that it can be safely distributed and prepared for safe use in patients forces companies to

innovate continuously through the development process. These innovations are important—they ensure consistent quality and safety of the product, and are essential to its effectiveness.

If enforceable patents are available for these types of innovations, the innovator is given an incentive to publicly disclose it, rather than hold it as a trade secret. That is a central purpose of the patent system—to provide an incentive to disclose innovations so others can learn from them and improve them further. It is plainly working—both original innovators and biosimilar manufacturers are innovating and securing patents on these types of innovations. The inherent design of the patent system also makes patent rights on these types of innovations narrow, which allows others to innovate around the original patented technology. That is how the patent system works to stimulate innovation—it pushes innovations into the public environment and forces others to innovate around the patented technology, which thereby advances the state of the art.

It is important to appreciate this inherent balance within the patent system when considering policies that would regulate patent enforcement and potentially cause forfeiture or impose limitations on patent rights. Patents on process and manufacturing innovations are important commercial assets, and often do not pose meaningful barriers to market entry.

Observations on the Proposed Legislation

I have not had sufficient time to study all of the legislation the Subcommittee is considering in this hearing. I can offer some preliminary observations on certain provisions that are found within the set of bills under consideration.

1. Purple Book Legislation

The legislation concerning the "Purple Book" for biological products raises certain practical concerns relating to obligations to list patents.

The Purple Book does not presently require patent listings analogous to the Orange Book for drugs, and there are good reasons for that policy. One is that the set of

patents that may be relevant to a first biosimilar product may not be relevant to the next biosimilar product (or any subsequent product). This is because the biosimilar products—including the precise nature of the active ingredient, the formulation of the product and the various manufacturing techniques used to produce it (including host cell choices, culturing and purification procedures, formulation choices, etc.)—will vary from one biosimilar product to the next. The BPCIA recognizes this with the way it calls for disclosure of manufacturing information from the biosimilar applicant to the reference product sponsor, which enables the reference product sponsor to identify patents that are relevant to that particular biosimilar product, including the particular technologies that biosimilar manufacturer is actually using.

Requiring patent listings for biological products thus raises a number of practical concerns. First, it is not possible for a reference product sponsor to know which patents are relevant to a biosimilar applicant's product until they see how that product is manufactured. Certainly, patents on the protein substance or on its use in particular therapeutic applications can be expected to be relevant, but many of the patents relating to how the product is manufactured and formulated may not. Moreover, it has not been my experience that it is difficult for a company to determine if patents or patent applications exist that might be relevant to a particular product. Patents and patent applications are published, and numerous tools exist for finding them and tracking their status. Listing patents in an FDA-hosted site that are already readily discoverable and are likely already known to a biosimilar manufacturer would not seem to add a lot of value while imposing administrative burdens on the FDA.

Second, legislation introduced in the Senate to require the listing of patents in the Purple Book would include a penalty of effective forfeiture of patents that are not properly listed. This type of severe penalty is unwarranted, given that relevant patents can be readily identified already from public sources, and that it is impossible for an innovator to know which patents might be relevant to any particular biosimilar manufacturer. It also will lead to a practice of over-listing of patents to avoid the potential forfeiture, which ultimately will eliminate the nominal benefit that might come from listing such patents.

Third, the legislation pending in this Subcommittee raises some practical concerns. For example, it calls for the reference product sponsor to identify patents relevant to the confidential manufacturing process of the biosimilar sponsor before and regardless of whether those patents are ever asserted. The BPCIA, however, mandates that the manufacturing information provided by the biosimilar sponsor during the patent identification process be maintained in strict confidence. A requirement to publicly disclose patents found to be relevant to the biosimilar sponsor's manufacturing process could compromise the confidentiality of the biosimilar's manufacturing processes and thus creates a tension within the BPCIA. I also note that the Supreme Court has held that the patent identification process is optional, which means the patent listings presumably would not be made if the biosimilar manufacturer opts out of the patent identification process. How the patent listing obligation would apply in such a scenario is hard to predict, and may not yield any benefits.

2. Legislation Implicating Patent Settlements

Certain of the bills pending before this Subcommittee would impose new reviews and restrictions on patent settlement agreements entered into between innovators and generic or biosimilar manufacturers. I believe these types of measures must be carefully considered to ensure they do not discourage pro-competitive conduct that can deliver biosimilar and generic versions of innovative products to the market sooner than might otherwise be possible through litigation where applicable patents have been successfully asserted. Patent settlements which allow a generic or biosimilar manufacturer to commence marketing of their products before expiration of valid patents advances the goal of accelerating market entry of the biosimilar or generic product and should not be discouraged when they are commercially feasible.

One bill would prohibit settlements where the biosimilar or generic manufacturer would receive anything of value from the reference product sponsor or NDA holder. What might be covered by this very broad language is hard to determine. That creates practical concerns for the entities considering a patent settlement, as every settlement invariably provides practical benefits to each side. For example, there may be provisions

in a settlement that involve technical cooperation between the companies outside the area of the particular product, which could serve pro-competitive and pro-patient goals. It would also be very difficult for the FTC to apply this standard, as it would require investigations into the potential value of provisions in the agreement, which are invariably subjective and linked to the particular parties involved.

The bill also would impose penalties in connection with patent settlements and would apply these standards retroactively to settlements that already have been entered into by the parties. This raises some serious concerns. For example, it would make conduct that the relevant antitrust authorities have already found proper to now be improper, and would potentially expose companies to liability long after they have taken actions based on good faith compliance with existing standards. It also appears to call for voiding of patent settlement agreements that have led to dismissal of the underlying patent litigation. It is not clear whether the reference product sponsor or NDA holder would be able to restart the dismissed patent litigation if the settlement that prompted termination of it were voided, which could thus indirectly lead to a forfeiture of the underlying patent rights.

3. Changes to Orange Book Patent Listings

Some of the bills under consideration by the Subcommittee propose to alter the parameters governing patents listed in the Orange Book. I raise two concerns regarding these proposals.

First, one provision would prohibit listing of patents that involve medical devices that incorporate a new drug product. It is unclear what the scope of this provision will actually be, but it does raise concerns that patents integral to a new drug product could be omitted from the Orange Book. For example, many examples exist of active ingredients that have been viable drug products because of the mechanisms used to deliver the drug to the patient. Often, those mechanisms fall under the definition of a medical device, and are integral to the therapeutic effectiveness and safety of the drug product. These patents should be able to be enforced like other patents that are integral to the drug product.

Second, the bill would allow the FDA to grant final approval to an abbreviated new drug application if the Patent Trial and Appeal Board (PTAB) issues a decision holding that a patent listed in the Orange Book is invalid. This raises several concerns. For example, decisions by the PTAB are almost always appealed to the Federal Circuit and are often reversed. If that occurs, and the generic manufacturer commences marketing of its product, the legitimate economic interests of the NDA holder derived from their valid patent will be impaired, and there can be market disruptions if marketing of the generic terminates. In addition, PTAB challenges occur outside the scheme of the Hatch-Waxman Act—they can be commenced before an ANDA applicant may file the application and before the NDA holder can assert the patent. Allowing this type of indirect challenge would undermine the carefully regulated scheme of the Hatch-Waxman Act that governs when patent challenges can be commenced.

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In conclusion, legislation that has the potential to foreclose commercially reasonable settlements, impair valid patent rights, or retroactively penalize entities that acted in good faith under current laws and policies needs to be very carefully considered. In addition, measures intended to accelerate market entry of biosimilar and generic products need to ensure that they do not disincentivize not only development of new drugs and biologics, but the innovations needed to manufacture them and deliver these products safely to the patients that need them.

Thank you for considering my views.

Ms. ESHOO. Thank you very much for your testimony.

It is a pleasure to welcome you, Mr. Carrier. Mr. Carrier is a distinguished professor at Rutgers Law School. You have 5 minutes for your testimony.

STATEMENT OF MICHAEL A. CARRIER

Mr. CARRIER. Thank you. Drug prices are too high, and one central reason why they are too high is that brand companies play all sorts of games to delay generic entry. Brands pay generics to delay entering the market. Brands deny samples the generics need to enter the market. Brands abuse the regulatory system, and as Ranking Member Burgess pointed out, we are going ruffle some feathers when we say that the brand companies cannot do this sort of conduct.

On the other hand, nothing that I say today will have anything to do with patents. Nothing that I say today will have anything to do with innovation. That is not at issue here.

My name is Michael Carrier. I am a distinguished professor at Rutgers Law School. I emphasize and focus on pharmaceutical antitrust law. I have written more than 115 articles, including 60 on pharmaceutical antitrust law. I write friend of the court briefs to courts on behalf of hundreds of professors, and I am frequently cited in the media and the courts.

The first thing that this committee can do is focus on samples. Under the Hatch-Waxman Act the generic was supposed to have a sample from a brand company, and that is how it can enter the market quicker. It doesn't have to replicate the costly clinical trials that brand companies have to do. The generic can do it a lot more easily. The problem is that when the brand company denies a sample that a generic needs the generic can't even get to the starting line. So you look at the nonREM setting where there is no safety concern at all. Take Pharma Bro, Martin Shkreli, jacked up the price 5,000 percent. Everyone focuses on that. No one focuses on the fact that the restricted distribution system is the reason that he could do this.

So when he said you can only get it through Walgreens specialty pharmacy and his official said, oh, we don't give it to generics that is a problem. The REM setting is a safety setting, and so the FDA is allowed and is supposed to have restrictions that deal with safety. Brand companies, however, have abused this. And they have said that we are not going to give you the sample even if you have a letter from the FDA that says that it is safe. We have all sorts of concerns. We don't have a duty to deal.

The FDA has tried mightily to solve this problem. It is hard to think of an FDA Commissioner doing more than Scott Gottlieb has to address this situation, but even so, it is still not enough to get samples in the hands of generics.

So the FDA can't solve the problem. Antitrust litigation is costly and nuanced and takes years, and so this Congress is the best place to do it. There are two great pieces of legislation I think the CREATES Act is even stronger because it would make clear that brand companies can't engage in these games that any excuse they have in relation to safety or product liability is addressed in the

legislation. So I am a big fan of the legislation, including the CREATES Act

Something else that this committee could do is focus on settlements, so Chairman Eshoo talked about two to tango. That is exactly what is going on here. Under the Hatch-Waxman Act the 180-day period was designed to encourage early generic entry. So let's say you have the brand company dancing on the dance floor all by itself and it is a dance floor of monopoly profits, what happens is that the goal was to have a generic that wants to break into the dance floor so consumers could get affordable medications.

Unfortunately, the 180-day provision has been completely twisted, so now you have a first filer who is rushing to be the first filer, going to tango with the brand company for years and all the meantime the consumers are paying monopoly prices and no other generic has an incentive to challenge the patent and enter the market.

And so the FAIR Generics Act would go a long way towards addressing this by dealing not just with the first filer but saying if you are the first to win District Court litigation that is what we want to incentivize. So I am a big fan of that legislation.

In terms of other settlements legislation FTC v. Actavis solved a lot of the problems. It didn't solve all the problems. Courts are still getting it wrong. There are still pay-for-delay settlements, so if you make clear that these settlements are illegal that would be incredibly helpful to the FTC and courts and as a reminder to courts themselves.

In terms of the Orange Book, there is a lot that could be done. The FDA plays a ministerial role. It does not remove patents from the Orange Book when the patents are declared invalid by a court or the Patent Trial and Appeal Board. It would be useful to do that. You have device patents like the EpiPen. Why is that in the Orange Book for decades keeping generics off the market? That is something that can be addressed, as well.

And then finally the Purple Book could be brought into the 21st Century. It is now a PDF. Let's make it searchable. Let's make it more like the Orange Book. So in short, these are incredibly important pieces of legislation. They will not affect patents. They will not affect innovation, but they will get affordable medicines into the hands of consumers that need them. Thank you.

[The prepared statement of Mr. Carrier follows:]

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Statement by Michael A. Carrier
Distinguished Professor, Rutgers Law School
March 13, 2019
to Health Subcommittee of House Committee on Energy & Commerce
on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"

I. Introduction

- A. Drug prices too high
  1. Brand drug companies abuse system by delaying generic entry
  2. Brands withhold samples needed by generics, pay generics not to enter market, and abuse regulatory system
- B. This conduct cannot be justified by patents or innovation
- C. Congress can address through legislation on samples, settlements, and regulatory fixes

II. My Background

- A. I have studied pharmaceutical antitrust law as co-author of leading IP/antitrust treatise; author of more than 115 articles (60 on pharmaceutical antitrust law); author of "amicus" briefs on behalf of hundreds of professors; and one frequently cited in media (1500+ times) and courts (including Supreme Court)

III. Sample denials: CREATES Act and FAST Generics Act

- A. Generics need samples to reach market but brands have denied them
  1. FDA has received 150 inquiries from generics unable to obtain samples; costs $5+ billion/year
  2. FDA powerless: its "generics are safe" letters ineffective; agency not examine competition issues
  3. Sample denials violate legislative provision that brands not use REMS to "block or delay" generics
- B. Brands have abused Single Shared REMS program, applicable when brand, generic each have REMS
  1. Have slow-walked negotiations, sometimes for years (e.g., Suboxone, Xyrem)
     a) FDA acts "after substantial delay" and "ha[s] to try and try and try and try, and then finally . . . declare defeat and . . . go ahead and let the generics have their own system."[1]
- C. Antitrust law uncertain – even if should be violation for conduct making no economic sense, courts could accept brands' arguments based on safety, product liability, and lack of duty to deal with rivals
- D. Sample denials
  1. H.R. 965, Creating and Restoring Equal Access to Equivalent Samples Act (CREATES) of 2019, offers simple fix, allowing targeted lawsuits to obtain samples
  2. Requirement that generic obtain "covered product authorization" addresses safety concerns
  3. Unequivocal limitation of liability addresses liability concerns
  4. Remedies of attorneys' fees/costs and monetary amount sufficient for deterrence will stop abuse
  5. H.R. 985, Fair Access for Safe and Timely (FAST) Generics Act of 2019, would allow HHS Secretary to require access to samples as condition of approval/licensing
- E. Shared REMS
  1. Bottleneck relieved through CREATES Act's "different, comparable" REMS, FAST Generics' 120-day waiver
- F. Legislation offers simple fix to non-REMS restrictions like Martin Shkreli's 5000%-price-hiked Daraprim
  1. 62 years after approval and for no apparent reason, Turing restricted distribution system; official "would block [generic] purchase" and company "do[es] [its] best to avoid generic competition."[2]

IV. Pay-for-Delay Settlements: Open 180-day Bottleneck

- A. Brands paying generics to delay entering market costs consumers $3.5 billion a year
- B. Pay-for-delay settlements reveal perversion of Hatch-Waxman Act (HWA)
  1. 180-day exclusivity period twisted from incentive to invalidate patents to bottleneck blocking entry
     a) By paying first-filer, brand delays entry by all generics, as 180-day period begins when generic enters
     b) Toothless forfeiture provisions apply after years-delayed appellate court decision
     c) Later-filing generics do not challenge patent: not obtain exclusivity, may lack standing
- C. Solution: expand universe of parties eligible for 180-day exclusivity
  1. H.R. 1506, Fair and Immediate Release (FAIR) of Generic Drugs Act, expands "first applicants" to include:
     a) Generics obtaining judicial invalidity/noninfringement decision
        (1) More likely to lead to competition than challenge-blocking settlement

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[1] *See* Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, 103 CORNELL LAW REVIEW 1, 41-47 (2017).

[2] *See* Michael A. Carrier, Nicole L. Levidow, & Aaron S. Kesselheim, *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERKELEY TECHNOLOGY LAW JOURNAL 1379, 1400 (2017).

b) Generics not sued for infringement
(1) Brands lack incentive to sue later filers (could invalidate patent); change allows earlier generic launch
2. 180-day incentive not needed: shared exclusivity not stop first-filing challenges by multiple generics, and presence of brands' own generics not reduce challenges even in small markets

D. Solution harnesses Congress's ability to directly address regulatory evasion
1. At oral argument in *FTC v. Actavis*, Justice Scalia stated that "Hatch-Waxman made a mistake" and Justice Kagan lamented the Act's "glitch . . . that the 180 days goes to the first filer" and that once the filer "is bought off, nobody else has the incentive" to challenge patents (Transcript, at 11, 35)

V. Pay-for-Delay Settlements: Illegality

A. H.R. 1499, Protecting Consumer Access to Generic Drugs Act of 2019, beneficial
B. Most important, creates framework of illegality applying when generic receives "anything of value" (including exclusive license) and delays "research . . ., development, manufacturing, marketing, or sales"
1. Illegality makes clear that pay-for-delay settlements anticompetitive and helps FTC prove cases in court
2. Parties allowed to settle cases based on patent, not payment
C. To prevent companies from treating antitrust liability as cost of doing business, FTC can recover penalty
D. H.R. 1499 would address errors like *AbbVie*, where brand provided generic with drug at price "well below what is customary" but court (despite recognizing deal's "large value") concluded it "was not a reverse payment."[3]
E. Two amendments to H.R. 1499 would make clear that courts cannot undermine landmark *FTC v. Actavis* decision:
1. Generic entry before end of patent term is not automatically procompetitive
a) Despite Supreme Court's overturning of scope-of-patent test, E.D. Pa. court in *AbbVie* and Administrative Law Judge in *Impax*[4] assumed pre-expiration entry procompetitive
2. Risk aversion is not a legitimate procompetitive justification
a) Third Circuit in *Wellbutrin*[5] relied on risk aversion (rejected by Supreme Court as defense) to dismiss argument that size of payment reflects patent weakness

VI. Orange Book Updating

A. Notice function
1. Generics, doctors, and consumers can learn critical information from Orange Book
2. H.R. 1503, Orange Book Transparency Act of 2019, useful in incorporating information on patent invalidity
3. Enhanced certainty from making clear that patents on drug delivery devices cannot be listed in Orange Book
B. Amendment to H.R. 1503 could prohibit listing of REMS patents in Orange Book[6]
1. Brand describes REMS in product label but generic must have same label (21 U.S.C. § 355(j)(4)(G))
2. Patents on REMS programs thus put generic between rock of FDA law ("Don't alter label!") and hard place of patent law ("Don't infringe patent!")
3. Not needed for innovation: Many REMS patents issued before *Alice* decision restricting patentable subject matter and not appear necessary to recover significant investment

VII. Purple Book Accessibility

A. Purple Book, applying to biologic products, not as useful as Orange Book
1. H.R. 1520, Purple Book Continuity Act of 2019, would make Purple Book searchable, enhancing usefulness
2. Helpful to consider types of biologic patents to be included in Purple Book

VIII. Conclusion

A. Drug prices too high; generic and biosimilar competition would lower them
B. Legislation on samples, settlements, and regulatory system would achieve goals without affecting patents or innovation

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[3] *FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015).

[4] *In the Matter of Impax Labs., Inc.*, Dkt. No. 9373, at 144, 146 (FTC ALJ Chappell May 18, 2018).

[5] *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017).

[6] *See* Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 BOSTON UNIVERSITY LAW REVIEW 1661 (2017).

Ms. ESHOO. Thank you very much. Well, that concludes the testimony from all of the witnesses, and I think each Member had a very strong sense that their brain was trying to catch up with what you were saying to absorb it all because you have comments—you have each made comments on not only what you agree on but how to strengthen the legislation and to fill in—let's see how I can describe it—where you think there is a blank somewhere in the legislation to strengthen it, but I think that collectively it has been excellent legislation.

Now, between—I would like to pursue both the orange and the purple because, Mr. Kushan, you were smiling when Mr. Carrier was testifying. So I will start with Mr. Carrier. How—synthesize for us where you think the improvements need to be made relative to the Orange Book and the Purple Book, and if you think the legislation regarding both comes up short?

Mr. CARRIER. So I think that one——

Ms. ESHOO. As quickly as you can.

Mr. CARRIER. So one problem with the Orange Book is that it does not make clear exactly when a patent is invalidated. When a patent is in the Orange Book that is very helpful——

Ms. ESHOO. Let me ask this because I don't know all that much about it. Why would something be carried in print when it is no longer in use?

Mr. CARRIER. So the FDA regulates the Orange Book. It is a listing of patents and drugs that go along with them, but the FDA is not checking every day to see what happens in the court system, in the Patent Trial and Appeal Board. So it is possible that you have a patent that is listed in the Orange Book, which gives the brand company an automatic 30-month stay where that is not the most up to date information. So if we get that——

Ms. ESHOO. Why not have something orange online?

Mr. CARRIER. So, yes, the Orange Book——

Ms. ESHOO. I mean, as soon as it is printed it is out of date.

Mr. CARRIER. So the Orange Book is online. It is just that some of the information is not as up to date as it could be, and so that is one improvement that could be done.

Ms. ESHOO. OK. Mr. Kushan?

Mr. KUSHAN. So I think—so I was smiling because I have downloaded the PDF for the Purple Book, and it is way less useful than the Orange Book, which is a very useful tool that——

Ms. ESHOO. Does the legislation address your concerns, though, that is what I want to know?

Mr. KUSHAN. So the issues that I see with the listing issues turn on the impact of these listing provisions. One of the things that Mr. Carrier had flagged was the idea of going in and updating patent status based on kind of current information on litigation around the patents or in something in the Patent and Trademark Office.

I think one of the concerns we have about going in and altering the status before there is a final determination about these patents is that you might have to change it later. There was a proposal I think in one of the bills that you would have to delist a patent if there was a decision of the Patent Trial and Appeal Board. Those are not final decisions, those are always appealed to the Federal

Circuit. It is much better to have a system where you can get a final outcome on the patent before you start making these changes.

It is also important to recognize that this is not an insular world. There is a very readily accessible information about the status of these outcomes in patent litigation they get into the news. So I think we have to just look at those very carefully and make sure we have stable system, thus people have more predictability, and I think, you know, more enhanced searchability, capability of the Purple Book certainly would be welcome.

One thing I did mention in the listing process for the patents for the biologics we really need to look at how we can do that as a practical matter because of that confidential information that we are looking at during the patent dance.

Ms. ESHOO. I appreciate that. Is there any witness that thinks that of the legislation that we are considering today and that you spoke to, do you all agree that it moves the needle to help consumers? Is there anyone that disagrees with that? Uh-oh, Mr. Kushan, you have a look on your face.

Mr. KUSHAN. No, I apologize. I don't want to dominate this hearing either.

Ms. ESHOO. You can tell that I take everything into consideration.

Mr. KUSHAN. I think you are making a lot of strong moves to help make the system more transparent. That is good——

Ms. ESHOO. And I appreciate your pointing out how important innovation is. We can do many, many things to lower drug prices to really—so that the consumer, the patients, the stories that Mr. Boutin told as well as the testimony of all of you and still obviously protect innovation because the patients depend on breakthroughs in order to address what is ailing them. So I think that it is a set of book ends.

With that I would now like to recognize the ranking member for his 5 minutes for questioning, Mr. Burgess.

Mr. BURGESS. I prefer the term Chief Republican.

Ms. ESHOO. Whatever you want.

Mr. BURGESS. So I know when we had this hearing in December of 2017 I think I made the comment, it is still applicable today, that if we don't understand the difference between Sovaldi and Daraprim we may very get—come to the wrong conclusions here, and several of you, Mr. Carrier, you brought up Daraprim, a medicine that has been around for a long time, really not protected by patent. Great medicine but it wasn't really something in breakthrough status, but because of the vagaries of the market now is—if I go on my GoodRX app I can buy it for $60,000 for a month's supply so that is a problem.

Sovaldi, a medicine that was developed to treat hepatitis—not treat hepatitis C, cure hepatitis C, and I made this point several times in this committee. I mean, that is a gift to humanity. Hepatitis C didn't even have a name when I was a resident at Parkland Hospital. We called it nonA/nonB hepatitis, and someone said, hey, that is hepatitis C, and the division of nomenclature said, yes, you are right, they blessed it hepatitis C, but there is a disease in 1977, 1978 didn't even have a name that now has a cure. I mean, that is a pretty good result.

So to balance the availability of medicines that will be affordable, and Mr. Boutin did a great job of illustrating why that is important. Same time innovation the world looks to the United States for innovation. I don't know of any other country that was going to cure hepatitis C, but the United States did, so thank you for that.

And actually and Mr. Davis or Mr. Barrueta you actually made the point in your testimony about the—for Kaiser the medicines to cure hepatitis C and actually the cost has come down. I have got your brief history of drug pricing from 2015, and, of course, there the concern was 2014 a lot of stuff went up, and I think the thesis was Sovaldi or Harvoni has cost, but now there has been without a generic actually but just different formulations and the price has come down, so competition did work. It may not have come down as much as Kaiser would like, but still it has come down, wouldn't you agree with that?

Mr. BARRUETA. I do. I do think, Congressman Burgess, one thing to really recognize here is the system the way it is currently designed has a major impact on where manufacturers choose to launch their prices, and signals are set based on the way the system is operated.

And so with the case of Sovaldi in particular there was tremendous concern that the choice to price that product at the upwards of 80, $90,000 reflected what the old therapy was, which was not very useful for very many people, but that drug was going to be used in a huge number of people. So you need to look at the whole of this.

Mr. BURGESS. Correct. And that is actually the point I was going to make. We are on the cusp of some rather dramatic cures, not just treatments but cures, and this committee is responsible for the Cures for the 21st Century. We worked on it for three Congresses. We have really pushed that along 60 Minutes, a show I don't normally watch but had a special on sickle-cell and curing sickle-cell. I mean, who would have ever thought that that was possible?

But we do need to think about how we are going to amortize the cost of research and development and paying for that innovation, how are we going to amortize that into the system because we could agree that Sovaldi nearly broke the bank of a provider like Kaiser and our State Medicaid organizations really felt the brunt of that. They had no way to prepare for that. They didn't know it was around the corner.

One of the things that I have talked about in this committee, I think Mr. Guthrie has a bill that would at least allow CMS to talk to a manufacturer before the FDA approves if it looks like something coming down the pipe is going to be pretty dramatic but dramatically expensive it would be good that people could begin to at least make some decisions that might soften the blow. And I think we are going to have to look, if you look at some of these gene therapies that are single, single administrations that cure blindness, hemophilia, muscular dystrophy, and these are things that we are going to have to figure out. You are right, the old way of pricing and that extrapolating that as using some formula may not work at the same time, and this committee understands the value of the Cures legislation that we did. We cannot interfere with the scientific discovery process.

Mr. Carrier, just one thing because you had it in your testimony a medicine I wasn't even familiar with Xyrem, that is patent protected until 2024, but the REMs on that is going to be significant because it can be a dangerous product in the wrong hands.

Ms. ESHOO. The gentleman's time is expired.

Mr. CARRIER. Repeat the last five seconds.

Mr. BURGESS. I said that the REMs is going to be significant—it is patent protected until 2024.

Ms. ESHOO. Why don't you let him answer because your time is expired?

Mr. CARRIER. So, yes, there is a concern when there are patents on REMs that is not really what the patent system is about. I couldn't agree more that innovation is absolutely crucial, but sometimes at the margins we are not talking about innovation just like the Daraprim example you mentioned and this one, as well.

Ms. ESHOO. Thank you. I now would like to recognize the chairman of the full committee, Mr. Pallone.

Mr. PALLONE. Thank you, Madame Chair. I wanted to start by asking Mr. Carrier a question and then move to Chip Davis, and, Chris, I want to acknowledge that Mr. Carrier is a professor at Rutgers Law School where I also went to school, so it is special to me that you are here today.

When the REMs program was put into place as part of the Food and Drug Administration Amendment Act of 2Congress contemplated and ultimately made it explicit that these safety protocols should not be use as a means to delay generic competition. Unfortunately, congressional intent has been obfuscated by delay tactics by branded manufacturers that have thwarted generic attempts to develop their own versions of drug products or to impede the ability to enter into a shared safety protocol.

This committee has been considering for some time now how to best ensure that congressional intent was upheld, and Congressman Welch and myself have advocated for market-based solutions that would allow for streamlined processes for accessing samples, resolving challenges in establishing REM safety protocols.

So initially, Mr. Carrier, some concerns have been raised that the CREATES Act, which of course is a main vehicle for dealing with this problem, could unintentionally incentivize frivolous lawsuits in order to obtain monetary penalties, rather than seriously pursuing samples for purposes of drug development. While this is suggested maybe that maybe the CREATES Act could lead to additional patent settlements. What are your thoughts on these claims? I mean, obviously I support the CREATES Act. I am only being devil's advocate here kind of get your feeling on some of these suggestions against it. Do you believe that CREATES could lead to a different type of gaming?

Mr. CARRIER. Absolutely not, and I do respect the brand companies for their creativity in coming up with arguments like these. For starters, the CREATES Act only applies to eligible product developers. You can tell really quickly if it is a generic that is trying to get the sample or a trial lawyer with slick backed hair. I mean, you can figure that out quickly. Will it lead to settlements? Absolutely not. The problem with settlements today is that you have patents involved. Generally we don't have patents here. And also

you have a 180-day exclusivity period that cues up that first generic that settles with the brand company. So when the brand settles with the first generic no other generic is able to enter the market.

Here that is not the case. The brand company would have to settle with every single generic that wants to enter the market. That is a lot harder than in the settlement context.

Mr. PALLONE. Thank you. And then Mr. Davis could you respond to the same question, then I want to ask you another question about CREATES.

Mr. DAVIS. Sure. Thank you, Chairman Pallone. I would completely associate AAM and our members with the comments of Professor Carrier. We do not see any concern about frivolous lawsuits. I think it is important to remember that the CREATES Act and the FAST Generics Act keep the FDA at the center of this issue and ensuring the safety, and certifying the safety, and integrity of whether it is the branded manufacturer handling their lot or a generic manufacturer subsequently.

So we have always supported a bill that kept the FDA in the center and ensuring that no matter who is handling the samples that they get certified by the FDA accordingly. The other thing that I think it is important to point out is that it is a very limited cause of action that is only triggered if a branded company fails to negotiate in good faith at fair market value. So it is a very limited window, and one quite frankly our members hope they never get to because it only reflects a failure of the ability to secure the samples through fair market value.

Mr. PALLONE. Chip let me ask you another question. You know the CREATES Act contemplates a legal pathway by which the generic manufacturer could access samples, as well as possibly a monetary penalty if the brand manufacturer refuses to allow access. And I understand that other enforcement mechanisms have also been contemplated in this path. But will you discuss AAM's perspective on the CREATES Act and what your members believe will be the strongest deterrent to gaming of the REMs requirement.

Mr. DAVIS. Yes. Thank you, again, Mr. Chairman, for the question. Again, our mindset is that a cause of action is only an issue of last resort that we hope we never have to get to be completely candid. The challenge is since REMs programs were created back as part of the Purdue for reauthorization in 2007 that bill specifically says REMs programs should not be used for anticompetitive purposes.

The problem is there is no enforcement provision. So unless there is a significant enforcement provision or risk of a significant penalty to the branded manufacturer the risk of having some sort of diluted remedy is that it just simply becomes the cost of doing business, and you are better off continuing the anticompetitive practices because the penalty on the back end won't be severe enough.

So we want to make sure that it is a very limited scope of action that is only triggered by a failure to negotiate in good faith, and at that point though there has to be something of significance to hopefully deter the actions that have now been going on for the better part of a decade.

Mr. PALLONE. Thank you. Thank you, Madam Chair.

Ms. ESHOO. Thank you, Mr. Chairman. It is a pleasure to recognize the former chairman of the full committee, the gentleman from Michigan, Mr. Upton.

Mr. UPTON. Well, thank you, Madam Chair. This is an important hearing, and I appreciate everyone's testimony, that is for sure. And as you all may know every one of us on this committee worked very hard on the 21st Century Cures Act. We are all cosponsors. We all worked our networks of folks. We were all pleased when President Obama signed it into law in 2016. And one of the issues that I have some concern about, Mr. Kushan, as we think about that legislation with the unintended consequences of hampering innovation in medicine.

In your testimony you cautioned against legislation that would undermine the value of patents because the patent system was developed in part to encourage innovators to bring their discoveries into the public, rather than keeping it as a trade secret, and thus, be able to recoup all the value. Can you speak more to that dynamic and how it is facilitating continuing innovation and biologics and biosimilars, something relatively new?

Mr. KUSHAN. Sure. One of the things I tried to point out in my written testimony was that we are seeing a lot of innovation in the biologic space both from innovators and from biosimilars. When you have to actually figure out how to make a product and build a plan and reengineer it to make that product, you make innovations. That is just what is happening in that environment.

Mr. UPTON. And that is different than the generic side of things.

Mr. KUSHAN. Correct. In the biologics space there is a much bigger investment needed to make these products, and what you are seeing with those investments is a lot of ancillary innovation. And I think one of the things that I didn't mention in my oral remarks, but I think I have heard it from a number of other panelists is when you are getting into a setting where you are trying to settle litigation those entities in the biologics space actually are very sophisticated companies. They are both innovators and biosimilar manufacturers, and there may be settings for those interactions where they are going cross-license their technology to each other. We don't want to discourage that behavior if you are ultimately benefitting the patients with a procompetitive settlement.

I think what is very important in that process is to make sure you don't have punitive sanctions on the value of the IP voiding them or having them held unenforceable. There are some ideas floating around with patent listing concepts that I think would raise concerns on that front, but I think it is very important to keep that dynamic that is generating this type of ancillary innovation in the industry.

Mr. UPTON. And I got to say I think you agree I am particularly concerned that existing settlements would suddenly become illegal because of the retroactive nature of some of the bills that we are considering today. Is that your impression, as well?

Mr. KUSHAN. Yes, there is one of the provisions in the bills that would kind of retroactively review some of the settlements that have already been entered into and, that is particularly troubling from a litigation perspective because you have companies who have relied on that settlement to then move forward with their commer-

cial activities. If those things somehow change if those are no longer allowed, then you are going to have a fairly significant disruption in the commercial activity of these companies.

Mr. UPTON. I will confess that I am not a lawyer. Most people would say good, but I think that we all recognize the problem of that. I yield the balance of my time back to Mr. Burgess.

Mr. BURGESS. Thank you, Mr. Former Chairman, chairman for life, chairman in exile. Mr. Davis, if I could ask you as you are well aware, there was a version of the CREATES Act in the last Congress that was worked on with stakeholders. This version of CREATES is a little bit different, and some of the private action are perhaps more aggressive than this version today. Would you support a version of CREATES that perhaps was modified to make it once again bipartisan?

Mr. DAVIS. Thank you for the question. I think from my perspective the current version in both the House and the Senate does enjoy wide bipartisan support with over 90 stakeholders. I was saying the other day that I am not sure of another piece of legislation that enjoys from an external stakeholder perspective the support of both Public Citizen and FreedomWorks as an example, so it is a pretty diverse group of people who have come to the realization that after 10 years of abuse the time has come to end this problem. To that extent——

Mr. BURGESS. That was the version from last Congress, correct?

Mr. DAVIS. That was actually the Senate version which has not been modified. So my short answer would be we have been and continue to be willing to work with anybody who is committed to solve the problem in a meaningful way. We think actually, Congressman, the real risk here is that if there are parties that say they want to work together with an intent to actually dilute the enforcement mechanisms then you get at the risk to my answer previously, which is there is not a sufficient back-end remedy to actually alter the behavior on the front end.

So provided at the end of the day there is that sufficient enforcement, we stand ready—have been and continuing to stand ready to work with anybody.

Mr. BURGESS. I thank you. I yield back to the gentleman from Michigan.

Mr. UPTON. My time has expired.

Ms. ESHOO. Thank you. I now would like to recognize the gentleman from Oregon, Mr. Schrader, for 5 minutes of testimony.

Mr. SCHRADER. Thank you, Madam Chair.

Ms. ESHOO. Questioning.

Mr. SCHRADER. Thank you very much for calling the hearing today, very important hearing. I think we can all agree that bringing generic drugs to market faster brings down costs for all. We should all support efforts to challenge abuses in the system that would delay getting generic drugs into the hands of patients. Getting these drugs to the market and into the hands is where I think we need to focus. I am encouraged by the record number of generic approvals and was a proud author in the last Congress of legislation to help create the competitive generic pathways therapy that frankly just in the last 6 months has brought five more generic drugs on to the market where no competition had existed before.

I would like to emphasize today that getting drugs into the approved pipeline isn't the same as getting them on the market. As we discussed yesterday with Secretary Azar every year we see companies get tentatively approved as first filer, complete the bulk of the application process, and then stop before getting final approval. According to HHS this happens an average of five times a year. Drug companies wait so long to market their drug that they effectively block subsequent filers which could help drive down costs.

The Secretary indicated this lasts for an average of 12 months, far longer than the 180-day incentive that Congress created. Five drugs times an extra 12 months of exclusivity means much higher costs for patients in the healthcare system.

Why has this happened? Well, Secretary Azar says there are times when applications have some deficiencies that need to be corrected in a timely manner, and there are other times when manufacturers struck a deal with brand manufacturers to refrain from moving their drug to the market.

My bill, which I introduced earlier this year bipartisanly with Mr. Carter will stop the practice of parking generic exclusivity by first filers. Under the BLOCKING Act when a first to file drug application is parked at the tentative approval stage and that is the only thing blocking the subsequent generic from coming to the market the first filers' 180 days of exclusivity begins to run. This concept has the support of the President and is part of his budget in the lowering drug costs section.

After our conversation with Secretary Azar yesterday the FDA got back to me with a data analysis that suggested this proposal might save $1.8 billion, and at this time I would like to ask unanimous consent to enter that into the record

Ms. ESHOO. So ordered.

[The information appears at the conclusion of the hearing.]

Mr. SCHRADER. And contrary to what some in the industry may want you to believe this bill does not revoke, diminish, or shorten any period of exclusivity for any first filer. Very simply, it puts manufacturers on notice and requires them to keep the ball rolling after they have started the application process.

So, question for Mr. Carrier if I may, some have noted, and it was—the Secretary testified on this yesterday that there are some provisions in law that do require a generic manufacturer to forfeit their 180-day exclusivity. In your testimony you describe these forfeiture provisions as toothless. Could you expand on what you mean by the fact that they are toothless?

Mr. CARRIER. The Medicare amendments of 2003 were designed to solve the problem of a generic not entering the market and forfeiting its exclusivity as a result. The problem is that the provisions were drafted in way that they only apply upon the later of two events, one of which is an Appellate Court decision, which could take place years down the road.

So there have been four settlements where the Appellate Court decision took place 6, 8, 11, and 13 years after the settlement was entered into. And so if forfeiture only kicks in a decade down the road in my mind it is toothless.

Then the other question is what incentive is there for a subsequent generic to actually bring one of these challenges if it is not

going to get a piece of the 180, and so those are the two reasons why I think it is toothless.

Mr. SCHRADER. Well, Secretary Azar agreed with you yesterday, and for the record I would like to note that we did have FDA input on this product. We have talked at length with the different manufacturers in the industry, and this is a bipartisan bill supported by the President of the United States.

Thank you, Madam Chair, and I appreciate your calling this hearing today. I yield back.

Ms. ESHOO. Thank you, Mr. Schrader, and thank you for your excellent, thoughtful work. It is a pleasure to recognize the gentleman from Virginia, Mr. Griffith, for 5 minutes.

Mr. GRIFFITH. Thank you very much, Madam Chair. Mr. Kushan and Mr. Karst, in your view would H.R. 1499, the Protecting Consumer Access to Generic Drugs Act or H.R. 1506, the FAIR Generics Act, make it easier or harder for a generic medicine to come to market?

Mr. KARST. Thank you very much. I actually think it would make it more difficult, and particularly on the FAIR Generics Act, which intertwines these concepts of patent settlement agreements and 180-day exclusivity. I am in the trenches every day working with generic drug manufacturers, dealing with these immensely complex scenarios on exclusivity and forfeiture, and adding these two together which are complicated enough themselves separately I think would slow down things, could lead to further litigation. I don't think they are as procompetitive as the law currently is, in fact.

Mr. GRIFFITH. Mr. Kushan.

Mr. KUSHAN. I generally share Mr. Karst's conclusion on this. On H.R. 1499 there seems to be kind of an idealized settlement defined, and it doesn't reflect some of the realities that I have seen when innovators are trying to find a way of settling a patent dispute with a generic. They tend to look at more variables that are going to be mutually beneficial, which is natural in any kind of settlement negotiation that are not going to disrupt the core point of delivering that product onto the market before the patent expires. And so, I think we just need to have kind of a broader mindset when we look at these settlement agreements to look at the bottom line, is it going to get the product on the market as quickly as possible and yield procompetitive advantages to the market.

Mr. GRIFFITH. So without significant amendment you all do not believe that the patients would benefit from these two bills if they were passed and signed into law. Is that correct?Without significant amendment.

Mr. KUSHAN. That is a hard question to answer, but my instinct is that it will make the negotiations much more complicated and less fruitful of what we are trying to do.

Mr. KARST. I fully agree. I think it will be a disincentive to—there won't be an incentive to settle, therefore, there are will an incentive to carry on litigation, and that is simply going to delay generic drug competition all that much more.

Mr. GRIFFITH. Thank you. Mr. Davis, in 2013 the Supreme Court ruled, as you know, in FTC versus Actavis that the so-called reverse payments from brand drug companies to generic companies with the intention of delaying the entry of a generic or biosimilar

pharmaceutical could be deemed anticompetitive. Consequently, according to the Federal Trade Commission the number of patent settlements involving so-called pay-for-delay agreements between brand companies and generic manufacturers has declined significantly. Can you explain if patent settlements may be useful in some cases and what some of the unintended consequences of eliminating patent settlements may be?

Mr. DAVIS. Sure, Congressman. Thank you for the question. I think it is—let me state up front that what has in the sort of public debate about patent settlements the term "pay-for-delay" has become almost all encompassing. To be clear, AAM and our members we do not support pay-for-delay agreements full stop. What we do support is the ability of private parties to negotiate in good faith if, in fact, it leads to the acceleration of generics coming to the market. And there have been, and the FTC issued a report post the Actavis decision in 2013 that the vast majority of agreements that have been reached subsequent to that seminal decision have been ones that have not been found to be anticompetitive.

The other thing I would add Congressman is I think it is really important when you look within the context of patent settlements that it is we would submit to this committee problematic and quite frankly dangerous to disassociate issues around patent settlements without thinking about the larger context and the bigger financial impact of patent abuses. If you will, if patent settlements are the symptom, patent abuses are the disease because if we actually don't take on a significant effort to address some of the things about evergreening and patent stacking that increasingly generic and biosimilar manufacturers are only left downstream with the ability to decide to enter into negotiations to try and get some clarity and certainty on having a date certain in which they can come to the market.

So our recommendation to the committee would be to make sure that as you are continuing to review legislation around patent settlements I think the Humira example is prima facie, which is without the ability for those companies to settle in 2023 and 2024 for a drug that was approved in 2002 whose main ingredient patent expired in 2014, the first competition would not be until 2034. And so my concern is that the legislation before you would not address that issue, and, in fact, may incentivize innovator companies to continue to throw as many patents as they can against a product in the late stage life cycle of the product.

Mr. GRIFFITH. I thank you very much, and I yield back.

Ms. ESHOO. I now would like to recognize the gentlewoman from California, Ms. Matsui.

Ms. MATSUI. Thank you very much, Madam Chair and thank you for having this hearing today. And I want to thank all of you for appearing here today.

I would like to focus for the moment on the potential for these policies to save real money for consumers. We are here to talk about high drug prices and some of the policy loopholes that allow drug manufacturers to maintain them for prolonged periods. We know that market competition lowers prices for consumers. That costs decreases exponentially when a third product comes on the

market and continues to decrease with each additional generic product introduced into the market.

These dynamics have incentivized some companies to extend their market monopolies for certain products well beyond the period of reward initially granted to them by the drug approval process. And I would like to better understand how consumers are being impacted by this behavior and how the policy we are considering here today could make a difference.

First of all, Mr. Barrueta, could you please describe for us why payers like Kaiser Permanente are concerned about generic drug access and how gaming of the drug approval system prevents such access. In short, how does generic drug utilization impact your members? I am just thinking of the patient.

Mr. BARRUETA. Thank you, Congresswoman Matsui. The ready availability of generics is really crucial to keeping the cost of prescription drug benefits stable over time. We do know that over time new drugs do come to the market, and if older drugs are not leaving branded status and becoming generically available in an orderly manner you see spikes in the cost of prescription drug benefits, and we have seen that for several years. That results ultimately in the need for health plans to generally modify the shape of those benefits. This is one of the reasons why we have seen increased deductibles in benefits and things like that.

And this is why we are very eager, particularly as we move toward much more expensive biotech drugs in the future to make sure that we are dealing with this problem up front because the problem that we have seen over the last 5 or 6 years where coverage has shrunk some as the cost of drugs has gotten higher and higher that is a dangerous warning sign for what is to come if there isn't some kind of approach that looks to the future of these drugs, as Congressman Burgess said million dollar drugs for various therapies start coming to market. We need a more rational way to do this.

Ms. MATSUI. OK. Mr. Barrueta the solutions the committee is considering today, which would have the most direct immediate impact on high drug prices? Does Kaiser Permanente prioritize passage of any of these policies?

Mr. BARRUETA. I think it would be great to move CREATES as soon as possible and get that on the market. I think that can help a lot.

Ms. MATSUI. And that would be it, you wouldn't prioritize the rest of them at all?

Mr. BARRUETA. I think it is really important that the committee is looking at all of this. I think the testimony we have heard today has demonstrated there are—careful consideration needs to be taken on all of these. I think they are all very well intentioned to do the right thing and it is a complicated process as we have heard from some of the experts who actually practice in this field. CREATES for us is just very clear and should move forward.

Ms. MATSUI. OK. Well then as we move forward to consider additional action on drug pricing, are there other policies that we should consider in the future?

Mr. BARRUETA. I do think that it would make sense to look more broadly around this. Some of this may not be within the jurisdic-

tion of the committee, but one of the—I didn't mean to imply anything, Congressman Burgess, but I do think there are some obvious targets. I think the way part B drugs are reimbursed in Medicare is driving higher and higher prices B part B. I think that that is an area that needs to be looked at. Reimbursement policy could be changed, disincent—to stop incenting the use of much more expensive drugs when less expensive drugs are available.

The Medicaid rebate program has in it a formula that deters discounting by drug manufacturers. I think that could be modified in a way to leave the States and the Medicaid programs at least whole and encourage competition in the marketplace. And then the last one and we have talked a little bit about this is I do think we have an excellent agency that is focused on competition and markets and protecting competition, and I think providing broader authority and broader resources to the Federal Trade Commission to take a more active role in examining how this market is actually operating would be beneficial.

Ms. MATSUI. OK. Well, thank you very much. We appreciate your ideas, and I yield back.

Ms. ESHOO. I thank the gentlewoman. Now I am pleased to recognize the gentleman from Kentucky, Mr. Guthrie.

Mr. GUTHRIE. Thank you, Madam Chair. Thanks for holding this meeting and the important meetings that we are having on prescription drug prices, and I have said for the last year or two that we need to deal with prescription drug prices and preferably through the marketplace and bringing competition to the marketplace, so this is an important hearing today, and I appreciate you doing that.

And, Mr. Karst, I want to kind of follow-up on my friend from Virginia's questioning of Mr. Davis, the pay-for-delay particularly. And I really looked at getting involved in moving this bill, and what I want to do is make sure that it is right, and it does what we want it to do. And I think Mr. Davis talked about—and I don't want any unintended consequences. I think you might have been the one who said sometimes it is like brain surgery, if you mess up you can really mess the problem up.

And I understand there were five out of 170 cases that have ruled to be noncompetitive that went before the Federal Trade Commission, and so how can these settlements in the pay-for-delay, how can these settlements actually be procompetitive?

Mr. KARST. Sure. Thank you very much, Congressman. So often times you have, of course, patents that extend years beyond any other type of regulatory exclusivities that may be granted by FDA, and, of course, you have generic manufacturers challenging these patents, paragraph 4 litigation, and if they have to continue to litigate these patents all the way to the end, as Mr. Carrier pointed out, sometimes these cases can go on up to the Federal Circuit for 10, 12 years after the initial litigation.

By being able to settle the litigation by some form of patent settlement agreement that allows for an earlier market entry date that is prior to the actual patent expiration not only means that companies, generic manufacturers can save millions of dollars when it comes to patent litigation, attorneys fees and what not, but they are also able to develop—put those moneys back into the com-

pany to develop other generic drugs to have more generic competition on the market, and they have date certain when they are going to be coming to market.

They could decide to go through the litigation process, and maybe they end up losing in the end. Well, what happens then, of course, is they are not even going to get approved until that patent expires years later than they might have otherwise been able to get on the market because of a settlement agreement. So in that respect I view these agreements as very—as procompetitive.

Mr. GUTHRIE. Well, are there cases where that brand has paid a generic and the generic doesn't pursue moving forward, and if so, what would be the solutions for that? That is what we want to prevent, and my understanding as I dig deeper into this it seems to be more the way you describe is the situation then just the generic accepting a payment not to come into the marketplace.

Mr. KARST. Well, it is not necessarily a payment. Whatever value you may exchange hands, I mean, again, it is for the benefit of getting that product on the market. I am a generic manufacturer, that is what I need to do. I need to get my product on the market and sooner rather than later.

And when you do the calculus of patent litigation the calculus may add up to if we are able to settle this patent litigation for an entry date certain that knocks off X number of years on the term of the patent for us to be able to get in, that is again procompetitive.

Mr. GUTHRIE. Thank you. Mr. Kushan, one of the concerns in the CREATES Act is it provides incentives for generic manufacturers to initiate litigation with the real purpose of extracting a settlement, rather than acquiring samples necessary to get a generic approval, I guess the argument for pay-for-delay they would rather have the settlement than access to the marketplace. Should we consider provisions that would deter these types of frivolous lawsuits?

Mr. KUSHAN. I will start by noting I am a patent litigator, so I don't have all knowing insights into some of these things. I do have instincts that when you create a right of action that gives an opportunity for a monetary outcome of the litigation you are just going to incentivize some activity that may not ultimately deliver what you are hoping for. I think this is a complicated topic. I have not had a lot of experience with the whole process of providing samples, but it seems like, you know, there should be a way to make sure that samples are made available for the purposes that they are needed to get the testing done to make these products available.

Mr. GUTHRIE. OK. I just have a few seconds, and Mr. Davis the prelude to an Oversight and Investigation hearing. Working with Congresswoman DeGette her staff has worked tirelessly to try to find real solutions for millions of Americans who depend on insulin. Can you explain why more generic insulins are not on the market, and how a March 2020 deadline for insulin approval will hurt generic insulins from coming to the marketplace?

Mr. DAVIS. I will do it as briefly as I can, Congressman, and thank you for your leadership on this issue. I think insulin is a classic case of a convergence of a number of troublesome and con-

cerning issue, not the least of which is the sort of the perverse rebate incentive system that we have now where list prices increase to absorb a larger demand for a rebate. There is late stage patenting with some of the insulins that are currently on the market.

And then to your specific question about the FDA's guidance about moving forward into March 2020 with what is being referred to as the regulatory dead zone, that was actually a requirement coming through the BPCIA that was passed in 2010, but the reality is if you have a pending biosimilar application pending with the agency you are actually going to have to go back to the drawing boards and actually start over again if we encroach upon that time frame.

Mr. GUTHRIE. My time has expired, so tune in March 11 for our next—April for our next hearing.

Mr. DAVIS. Thank you for your leadership on it because it is a very real issue.

Ms. ESHOO. I allowed the gentleman to finish his answer because I think that it is important that we hear the answers, but we will be following up with you, Mr. Davis. Thank you very much.

I now would like to recognize the gentleman from California, Mr. Cárdenas, for his 5 minutes of questioning.

Mr. CÁRDENAS. Thank you, Madam Chair. I would like to thank the ranking member, as well, for agendizing this important hearing. I hope that the Americans are watching because 1 out of every $5 in Americans' wallets somehow some way goes back into their healthcare needs, and this is an important aspect of that. So and also, I would like to thank the witnesses for coming forward and giving us your expertise and your perspectives, and when it comes to prescription drug pricing it is a complicated topic, but it is one that impacts the lives of Americans all over the country.

There are many moving pieces here, but I want to focus for a moment on biosimilar entry to the market. Despite the fact that the FDA has approved 17 biosimilars in the U.S., only 7 are on the market and available to providers and patients. This is a sharp contrast to the experience in Europe where more than 50 biosimilars are available. While it is true the Europe regulatory experience with biosimilars is more mature than here in the U.S. I am worried that if we do not start to address the barriers to biosimilar entry sooner than later patients will not be able to realize the benefits.

We know that spending on specialty drugs, which include biologics, has grown rapidly and is now nearly half of all of our spending. Biosimilars hold the potential to help cut down these costs with marked—with marketed biosimilars being priced an average of 40 percent less than the biologic.

So my first question is to you, Mr. Barrueta. I was impressed to learn that Kaiser Permanente has taken such a leading stance on biosimilar utilization, but what is the biosimilar utilization rate for Kaiser Permanente, and what led Kaiser to take such an aggressive stance on generic and biosimilar utilization?

Mr. BARRUETA. Thanks Congressman Cárdenas. We are using biosimilars as they are available pretty quite intensively, so I mentioned in my testimony that on one drug we are over 75 percent use of the biosimilar as opposed to the referenced product. We have

intensive use of Zarzio over Neupogen as another example, and, in fact, that is one where the data that we are able to see within our clinical records is demonstrating that drug is performing excellently. So we are having the European experience on biosimilars within Kaiser Permanente in many respects.

I think the critical thing is to make sure that good information is available to practitioners across the country who are faced with the opportunity to consider biosimilars for their patients and to make sure there is a regular source of objective unbiased and very solid information, and I think it would be important to use the Governmental resources that are charged with bringing information forward to make that available.

Mr. CÁRDENAS. OK. In your opinion, what are the key barriers that are blocking or delaying biosimilar entry into the marketplace today in America?

Mr. BARRUETA. I think it is clear what we have heard much of the testimony today that the patent thicket problem, I think, is inevitably a problem. I do think that as Mr. Davis said it is hard to separate the issues of some of the conduct that is going on in the existing system versus just the ability to throw vast numbers of patents forward, and there is a need to look at this broadly as the committee is today and try to create more transparency and more clarity to allow these things to come to market faster.

Mr. CÁRDENAS. There are some manufacturers that have benefitted from several loopholes in our current regulations, including agreeing to multiple patent settlements to further delay competition. In some cases, these products lack competition in the U.S. but have several competitors on the market in Europe and much lower list prices there as a result.

Again, Mr. Barrueta, will the legislation we are considering today help to close some of these loopholes and get competition to the market more quickly in America?

Mr. BARRUETA. I think it is a start. I think it is a move in the right direction. I think we have heard it is a multifaceted problem, but certainly pay-for-delay problems continue to exist that there should be further examination on these even moving forward. Whether that is the total reason why some of these are delayed as opposed to the broader patent thicket problem it is hard to pull apart, but I think absolutely what is being considered is a step in the right direction.

Mr. CÁRDENAS. I believe Congress has a role to play in this in correcting this problem, and hopefully we will be able to advance some legislation in the right partisan manner so that we can get this through for the American people.

My time having expired, I yield back. Thank you, Madam Chair.

Ms. ESHOO. I thank the gentleman, and just for the record on the issue of biosimilars, the legislation that created the pathway for biosimilars to actually move to generic was the legislation of the late Senator Kennedy and myself. So anything that blocks that from occurring we are going to do a deep dive on.

I now would like to recognize the ranking member of the full committee, Mr. Walden, of Oregon.

Mr. WALDEN. Good morning, Madam Chair, and thanks for recognizing me for questions. Mr. Boutin, H.R. 938, the BLOCKING

Act has bipartisan support on this subcommittee, and I understand that the goal of the legislation is to prompt generic manufacturers to launch their products as early as possible. Can you walk us through the issues in the market currently in the way this bill attempts to resolve those issues?

Mr. BOUTIN. I can tell you on that issue the National Health Council has not taken a formal position, but I will tell you that we are very supportive of the intent of this legislation. I know looking more closely at how we can help ensure that generics are getting to market as quickly as possible.

Mr. WALDEN. All right. Mr.—and I probably will get this wrong, Barrueta.

Mr. BARRUETA. Barrueta.

Mr. WALDEN. Barrueta all right. What was the 2018 operating revenue of Kaiser Permanente?

Mr. BARRUETA. The operating——

Ms. ESHOO. Turn your microphone on.

Mr. WALDEN. I am told 79.7, so——

Mr. BARRUETA. Just under 80.

Mr. WALDEN. Almost 80. What kind of impact would losing $79.7 billion have on your organization?

Mr. BARRUETA. That would be very bad.

Mr. WALDEN. It wouldn't help your employees, would it? Would you expect your company to have to lay off some workers, and how might it impact your organization's ability to continue operations?

Mr. BARRUETA. The loss of revenue obviously is something that any business has to accommodate itself to.

Mr. WALDEN. And we are all obviously interested in finding a powerful deterrent for bad actors, but I want to be sure we all understand what is at stake we are talking about revenue not profit or actual damages. As you well know there is a big difference there.

Mr. Davis, Mr. Burgess touched on some of the concerns he has about the unintended consequences of the pay-for-delay bill, and I think it is an important issue to consider fully. Can you provide some additional insight on how the agreements actually work, and would you say that they lead to earlier competition than we would otherwise see on the market?

Mr. DAVIS. Yes, thank you, Congressman Walden, for the question. So the short answer is, yes, there are situations, and I think the FTC has spoken to this in the report I referenced earlier, that in the wake of the Supreme Court's guidance in the seminal decision back in 2013 about their scrutiny that they would apply to a transferral of anything of value that the number of anticompetitive agreements as determined by the FTC has dropped significantly. That is a good thing. It is a good thing for the market. We support more market-based competition. In fact, competition if you will, is the DNA of the generic and biosimilar sector.

What we want to do is make sure that as our companies are doing everything in their power to get safe, effective, and affordable generics or biosimilars to the market as quickly as possible is that in those instances where settling, whether it be because of late stage patent stacking or patent abuse and filings the generic companies don't generate the revenue the brands do, so even in litiga-

tion there is a potential that they will get worn out of resources to the point about loss of revenue where they cannot continue. There is not a generic company that is going to be able to debate in court 100 pending patents for way of example.

So to not have the ability to settle on a date certain admittedly quite frankly because of certain patent abuses one that is longer out than they would have liked to otherwise is still important to make sure that they can preserve so they have some clarity and certainty about being able to go forward on a certain date. We used to have that complete—to be candid as an industry, and that is getting away from us year over year as the absolute certainty of when our manufacturers are going to be able to come to market with a competitive product.

Mr. WALDEN. All right. Anybody else want to add anything to that? Yes.

Mr. KUSHAN. I have just heard a few times the concerns about these patent thicket issues, and I want to make sure that we recognize that it is a slightly more nuanced circumstance. A lot of times the patents that come out later are very narrow, and when you are an innovator or when you are a biosimilar manufacturer you can make a choice whether to use the technology that is covered by the patent or not use it. And so when you look at all these patents, there are ways around the patents that are not involving invalidation of the patents.

It is important when we engage in this discussion to make sure that we don't kind of oversimplify the patent issue into an assumption that all patents do the same thing. Some are very narrow, some dominate the product, but you have to look at the actual obstacles if there are any that are in front of the biosimilar manufacturer and how they might best navigate around those obstacles.

Mr. WALDEN. All right. I see Mr. Carrier wants to say something. I have 14 seconds, it is all yours.

Mr. CARRIER. Very quickly, certainty for the brand and the generic companies is a lot of what we have talked about today, but on the other hand the Supreme Court in Actavis said it is the risk of competition that is the anticompetitive harm. Nine out of ten of these patents are not on the active ingredient, let's litigate them.

Mr. WALDEN. Thank you. Thank you, Madam Chair.

Ms. ESHOO. Thank you. Let's see, who is next? Mr. Welch of Vermont, one of the key members of our committee whose name is on more than one of the bills that we are considering today, you are recognized for 5 minutes.

Mr. WELCH. Thank you very much, Madam Chair. It is kind of exciting to be here because we are actually on the threshold of doing something, and that is something that eludes us in Congress, so it is nice to show up for work today. And we are actually building on work that was done when Mr. Burgess was the chair of this subcommittee and Ms. Eshoo was following on. So I am pretty excited.

The second thing is I really appreciated the testimony. It is like you all like know something about what you are talking about, and that is refreshing, as well. And I have got a request for everybody because you have been talking concretely about legislation, and one of the big challenges around here is to start getting into the details.

So if you have specific suggestions about how any of these bills can be improved, I think that would be of great interest to our committee because we want to get this right. And you have concrete, practical knowledge and experience that can help us do that. So my request to you is to send in your bullet points about areas on each of these bills where you have improvements. So thank you. But I want to just make a few comments and ask a few questions.

Mr. Davis, you said something that makes total sense to me, and that is that we want a deal on the front end where we eliminate patent abuse, so that we don't have to argue on the back end where no matter what the remedy is it is going to be tough. Can you just elaborate a little bit on that?

Mr. DAVIS. Sure, happy to, Congressman, and thank you for your sustained leadership on the issue of REMS abuse. It is greatly appreciated.

The larger dynamic in terms of—and again, I want to be clear here—that the generic and biosimilar industries recognize the importance of strong patent protection of intellectual property. We like to say that we rely every bit——

Mr. WELCH. You have got to be brief here because I only have 5 minutes.

Mr. DAVIS. So—but what we have more of a concern with, is, after sort of the initial filings on the patent and the product comes to market, as it is nearing the end of its product lifecycle, you see a lot of subsequent filings, particularly on expensive specialty drugs that further delay competition.

Mr. WELCH. OK. And, Mr. Carrier, an amazing number of articles you have written, congratulations and thank you for your contribution, but one of the pushbacks that we have had from branded pharma is that if we do anything about pricing, it is going to affect innovation. And I heard you say—and I just want to make sure I am right—that the various proposals that are under consideration today would not, in your view, adversely affect innovation?

Mr. CARRIER. That is correct. And so that is always the argument that the brand companies offer—if you do anything at all, that is going to hurt innovation. On the other hand, what is complicated about this area is that we have innovation on the one hand and generic competition on the other.

You look at Hatch-Waxman. Half of it is for innovation. Half of it is for generic competition. The brand companies have gotten everything they have wanted for innovation—the 30-month stay, the patent term extension, the nonpatent market exclusivity. But when it comes to the generic side, like the 180, they have now taken that for themselves. There has to be something there for generic competition.

Mr. WELCH. All right. Thank you for making that point. Mr. Barrueta, I want to ask you, do you have a view on the pros and cons of CREATES versus FAST? I am a cosponsor of both pieces of legislation, but I want you to tell us what you think is—should we combine them, or do you have a view on which one would be more effective?

Mr. BARRUETA. I guess my comment is probably more of a process one. Whichever one you can get done more quickly, I would go with that.

Mr. WELCH. Either way.

Now, Mr. Karst, you were talking about litigation. I have a confession. In addition to now being an active politician, I am a recovering trial lawyer.

Mr. KARST. OK.

Mr. WELCH. And public approval about 3 percent. I don't like litigation, all right? It just—it is the last resort, and there are other agendas that are usually involved in it. And do you see a way where we can try to do what Mr. Carrier is talking about, protect intellectual property and innovation, but on the other hand, spur biologics and generics? You know, you seem to be raising some questions about the necessity litigation, and I would like to get away from that, really, by doing what Mr. Davis is suggesting.

Mr. KARST. Yes, it is—as, of course, a lawyer, litigation is part of my job, but I was really raising that in the context of the BLOCKING Act, which, again, I am in the trenches all day when it comes to 180-day exclusivity generic drug approval, and anything that makes an amazingly complex law have all that much more complex tapestry is simply not good, in my opinion.

Mr. WELCH. Well, send us your suggestions.

Mr. KARST. This is in the context of the—yes, certainly—the BLOCKING Act, which I——

Mr. WELCH. Right.

Mr. KARST [continuing]. Just don't think is necessary, and it is just going to lead unnecessarily to more litigation.

Mr. WELCH. Yes, I mean, see—I know my time is up, but this is where there are some common ground here. We all want to protect innovation, but we want to get the prices down and make it affordable. So thank you. I yield back.

Ms. ESHOO. I thank the gentleman. It is a pleasure to recognize my favorite Greek in the Congress, the gentleman from Florida, Mr. Bilirakis.

Mr. BILIRAKIS. Thank you very much. I appreciate that, Madam Chair. Thank you for holding this hearing, by the way. This is a priority for all of us, because our constituents talk about this all the time, again, the high prices—the high, prescription drug prices. So we must lower the prescription drug prices, and I hear this from our veteran's population, our senior population, but the general population.

So I remain committed to working with my colleagues on both sides of the aisle to achieve that desired result in a way that does not undermine progress and that has already been made, so—the progress that has been made. And I agree with Representative Welch, I appreciate your testimony, and keep sending us your suggestions, because it means so very much. We have got to get this right.

Mr. Davis, can you share with us what is currently working and how we might double down on these efforts? That is the bottom line.

Mr. DAVIS. Sure. Congressman, thank you for the question.

I think when you look at the bills that are before you, I think both transparency bills, on the Orange and Purple Book, are, as has been referenced before by experts far greater than I, a really positive step in the right direction, and AAM is supporting both the

CREATES and FAST Generics Act that are also under consideration here.

I think one other area that is really important that hasn't been touched on yet today because it is not reflected in a bill currently before the committee, but relates to—and I think Mr. Barrueta's talked about how biosimilar uptake has been so significant at Kaiser—is about benefit design and formulary placement and the importance of ensuring that when generics and biosimilars get onto the market that they have a preferred position on the formulary.

We actually have an increasing case year over year, where follow-on competition from an out-of-pocket cost perspective may be more expensive because of agreements between originators and plans than the follow-on competition. If that happens, I would submit to you that Hatch-Waxman and BPCIA don't work. So ultimately now, and a credit to CMS, they are looking at this very issue as we speak for the 2020 Part D plans.

And so we encourage any Member of Congress who wants to make sure that generics are on a generic tier, biosimilars are on a biosimilars tier, and that the out-of-pocket costs, which, as we all know is what consumers and patients are really focused on, is making sure that those are lower for the subsequent, low-cost alternative as opposed to being higher.

Mr. BILIRAKIS. Thank you. Very recently this committee passed legislation to address the products with limited competition by creating the competitive generics therapy Program at FBA, also known as the Schrader-Bilirakis bill, and it extended the 180-day exclusivity to products without competition, and by all accounts, the program has been successful, with FDA receiving over 100 applications from generics manufacturers looking to bring competition to these products.

To me, this is a perfect example of the value that a 180-day exclusivity holds for generic manufacturers. But my concern with some of the bills we are discussing today, that, you know, we have a solution in search of a problem and should we move forward. The consequences of undermining the 180-day exclusivity and the adverse effect it may have on generics.

Mr. Karst—and you have touched on this—actually the entire panel has but let me ask the question again. In your opening statement, you stated the BLOCKING Act is not necessary. Why is that, and could you elaborate more? You referenced the medical maxim in your testimony, do not harm, and we don't want to harm. Could this bill end up weakening the 180-day exclusivity that has proven to be such a powerful incentive for bringing generics to market as quickly as possible?

Mr. KARST. Thank you very much for your questions, Congressman Bilirakis. And as an initial matter, thank you very much for the CGT, the competitive generic therapy legislation. It has been—it has been a smashing success. I can tell you, working with a lot of companies in the generic drug industry, this is—this is very important to them, and I am constantly working with companies to get the designations and the approvals, and companies are very much responding to your legislation and Congressman Schrader's legislation.

On the BLOCKING Act, quite simply, I don't think the bill is necessary, because, one, FDA already has the statutory and regulatory authority it needs to address the problem. Now, this has been, I guess, characterized by Secretary Azar as squatting on exclusivity, and it is not, I don't think, an accurate description of the situation.

In fact, these companies may, for one reason or another, whether it is due to FDA or their own fault, unable to get final approval, but FDA does have authority under the statute to deal with that situation already. Putting new provisions into the statute that are amazingly complex, again, not only will lead to litigation, but they are so complex in nature that I am afraid that it is going to significantly hurt the 180-day exclusivity incentive.

Mr. BILIRAKIS. Thank you.

Madam Chair, I will yield back to my favorite Syrian-Armenian chairman. Thank you.

Ms. ESHOO. We really got something going here.

It is a pleasure to recognize the gentleman from New Mexico, Mr. Luján.

Mr. LUJÁN. Thank you very much, Madam Chair.

Issues with REMS programs have been coming up for years. These requirements are meant to help ensure the safe use of certain drugs. Unfortunately, we have heard testimony over the years that REMS have been gamed to delay generic drug development activities. The FDA Commissioner has said that REMS abuse needs to stop, and the agency has taken a number of steps to try to facilitate generic access to samples.

I am concerned, though, that some have tried to argue that such access by generic drug developers could put patient safety at risk. Both the CREATES Act and FAST Generics Act lay out a process by which generic manufacturers could access samples of a branded drug product, provided that certain conditions have been met.

Ms. Kennedy, can you please describe the kind of testing you might do on a product before it comes to market? What do you have to show the agency to obtain approval?

Ms. KENNEDY. Yes. Delighted to answer. As the only manufacturer who gets up every day to lower healthcare and costs to American patients on this panel, I'm——

Ms. ESHOO. Move your microphone. Maybe it is not on. We really want to hear from you.

Ms. KENNEDY. I am pretty loud anyway.

Ms. ESHOO. There you are.

Ms. KENNEDY. OK. And I like your first name. At any rate, I would like to say that we are absolutely equipped with all the innovation and knowledge that we need to deformulate any brand product on the market with the exception of some of the biologics.

And as such, we are hoping that it is made easier by Congress and others to get those REM samples and make sure that we can begin our innovative process, and from that, we then are expected to prove to the FDA, with regular standards in place, that we are qualitatively and quantitatively equal and efficacious to the brand product.

As such, we are doing that over and over again, and particularly in the Part B Medicare space, and that is truly lowering the cost

of drugs to American patients, because our drugs that we are making as generics today are the 100 top movers list. They are taken by emphysema patients and others four times a day, and we hope to expand that as other drugs are—are closing—closing to near the end of their patent life.

And we hope that the Congress and all of the laws that will be enacted as a part of what we are talking about today, encourage us and help us to get our products to market and truly lower the cost of healthcare. That is where we are.

Mr. LUJÁN. Ms. Kennedy, can you touch on the safety as well——

Ms. KENNEDY. Yes.

Mr. LUJÁN. [continuing]. That you have to be attentive to, to ensure the product is, in fact, safe?

Ms. KENNEDY. Yes, we have to prove every test that the brand innovator has to prove, and we have also other tests required of us if we, for example, move to a different container closure, something that would be innovative and perhaps a less expensive way to package those products. We are required to test from soup to nuts, all C of A's must be passed, all matters of assay identity, osmolarity and all the other tests, including sterility, must be passed. So the quality is not at issue. We will not receive approval unless we are perfectly 100 percent efficacious or better than the brand.

Mr. LUJÁN. So, Mr. Davis, based on your review of the CREATES Act, do you believe that this legislation changes the safety standard or patient protections that are currently in place for equivalent branded products, and do you believe the bill opens a possibility of additional risk to patients?

Mr. DAVIS. So I believe it maintains the level of safety certification requirements that the FDA has, and actually puts more, sort of, teeth into it, Congressman. I would associate our comments with everything that I think was perfectly articulated by Ms. Kennedy as well. I do not think it exposes anyone along the continuum to any increased risk of safety whatsoever, because we actually trust the FDA to get it right.

Mr. LUJÁN. Mr. Davis and Ms. Kennedy, do you believe that either the CREATES Act or the FAST Generics Act would hamper the FDA's ability to ensure all drugs, regardless of whether they are brand or generic, are safe and effective and adequately protect against patient safety risks? Mr. Davis?

Mr. DAVIS. None whatsoever.

Mr. LUJÁN. Ms. Kennedy?

Ms. KENNEDY. Agreed. Their governance is what is expected of us. That is the law.

Mr. LUJÁN. And I guess as I close, Madam Chair, I take comfort in knowing that both pieces of legislation preserve a process by which the FDA can register any concerns with that plan before the samples are transferred, which is also something that is important for us to be noting as we move forward with consideration of legislation.

With that I yield back the balance of my time.

Ms. ESHOO. I thank the gentleman.

I now would like to recognize the gentleman from Indiana, Dr. Bucshon.

Mr. BUCSHON. Thank you, Madam Chairwoman.

Mr. Davis, I want to clarify, earlier you said—you listed a long list of people that supported the CREATES Act, and I want to clarify the version of that that you are talking about. The version was introduced to this Congress—or is this a previous version, and I think you mentioned it might have been the previous Senate version. Can you clarify that?

Mr. DAVIS. Yes, Congressman. Thank you for the question. So, yes, the list of supporters of which AAM is one, that has been tracked as actually a list that has been growing year over year, as this problem has become more significant, dating back to 2007 when the REMS programs were created. So that list applied to the version that was being considered last fall, in the Senate. The CREATES Act that actually passed out of the Judiciary Committee, is, I believe, the one where all of those stakeholders actually wrote a letter in support.

Mr. BUCSHON. OK, in that vein, I want to be able to support a version of the CREATES Act, but the current version seems to me, it could potentially and perversely incentivize litigation. As currently drafted, it appears that the generic company could simply not accept the valid offer from a brand manufacturer and go to court because—understanding the damages available to them could be much more lucrative. If an offer to sell samples on commercially reasonable, market-based terms has been made, should a generic be able to reject that offer and go to court?

Mr. DAVIS. I think the issue will be determining what fair market value is. As they always say, beauty is in the eye of the beholder in the negotiations. So I think that is actually one of——

Mr. BUCSHON. But that is defined in the law, right?

Mr. DAVIS. I am sorry?

Mr. BUCSHON. What fair market value is, is——

Mr. DAVIS. That would actually be based upon what is available in the marketplace, what the originator would be offering to sell to the generic manufacturer.

Mr. BUCSHON. Right, so commercially reasonable market based. I mean, I am not a lawyer, but——

Mr. DAVIS. Correct.

Mr. BUCSHON [continuing]. That is probably a definable, legal term, I would imagine, correct?

Mr. DAVIS. Correct.

Mr. BUCSHON. So would you maybe then—because since you were talking about the one that were supporting was the previous version last fall, and would you then support potentially adding language to the current version that might clarify that that type of scenario wouldn't unfold?

Mr. DAVIS. I would have to see the language, sir, and we are happy to take a look at the proposed language. I think from our perspective; the real issue is making sure this problem gets solved now.

Mr. BUCSHON. OK, great. Anyone else want to comment on that? Do you have any other comments?

Ms. KENNEDY. I think we have to encourage competition at every turn. We look to you guys for guidance and keeping people in their

lanes and really putting a stop to the gaming and the things that we are faced with.

Mr. BUCSHON. Well I don't think anyone disagrees——

Ms. KENNEDY. We are ready to serve.

Mr. BUCSHON. Yes, I don't think anyone disagrees with that.

Mr. CARRIER. And one other thing on litigation——

Mr. BUCSHON. Yes.

Mr. CARRIER [continuing]. Sure, it sounds pretty crazy, but nothing else has worked. And you have the FDA Commissioner saying, we are trying everything, it is not working, cut out the shenanigans. If you have deterrents and you have attorneys' fees, then finally the brand companies might wake up and say it is not worth the cost of doing business in this case.

Mr. BUCSHON. So then maybe that, you know, the language, "commercially reasonable and market-based" is not strong enough and that could be an area that could be strengthened to make sure that companies aren't purposefully turning down settlements that could be reasonable and commercially reasonable, in order to litigate? Mr. Karst, do you have a comment on that?

Mr. KARST. We are typically talking—I mean, again, for the amount of product we are talking about, maybe several hundred pills or tablets or capsules. So we are not probably talking about, in the end, a significant cost in the overall development program here for that generic manufacturer.

Mr. BUCSHON. But it is a very complicated subject, and I am not a lawyer. That is why I am asking you all.

Mr. DAVIS. Congressman, I would only add in the discussions that we have had with our members who were engaged in this and have been frustrated for the better part of a decade, I have never heard anybody talk about the interests in actually being able to go to court and sue on the grounds of not being able to recover as opposed to their interest in getting the samples, to bring product to park that so patients would benefit.

Mr. BUCSHON. Fair enough. Yes, I was a cardiovascular surgeon before, so obviously I am averse to frivolous litigation. And, you know, in all of our specialties, as providers, we all—if you practice long enough, you have to go through that process. And so, you know, anything that might potentially exacerbate that type of a problem, and whatever our solution is, to this issue, which we all agree needs to be addressed, is something that I wouldn't—I wouldn't support. So with that, I yield back.

Ms. ESHOO. Thank you, Doctor.

I now would like to recognize the gentlewoman from New Hampshire, Ms. Kuster, 5 minutes of questioning.

Ms. KUSTER. Thank you, Madam Chair, I appreciate it.

One of the most egregious abuses that we are discussing today is the abuse of measures intended to provide additional safety protections to consumers, as we have discussed, commonly known as REMS, risk evaluation and mitigation strategies, and plans that the FDA requires companies to develop as a response to a particularly serious safety risk posed by the drug.

At the front end of development, some companies are citing these REMS requirements as a reason not to provide product samples to generic drug developers for bioequivalence testing that supports

their drug applications. And on the back end of development, some branded drug manufacturers are negotiating in bad faith with generic developers to enter one—into one single system REMS.

So let me start, Mr. Davis, with you, if I could. Please describe for us the various safety measures in place to ensure that generic drugs come to market with the same level of safety as their branded counterparts. I know that is a broad question. Have in mind, I have 5 minutes.

Mr. DAVIS. Congresswoman, thank you for the question. I will try to be as brief as possible. I think the requirements are the same, right, that the generic manufacturers have to meet in terms of convincing the FDA from a pharmaco-vigilance perspective that we will adhere to the same standards and criteria as set forth for the originators.

As part of that, when it comes to actually doing the reverse engineering, if you will, the FDA is actually required to look at the generic manufacturer, look at a company like Ms. Kennedy's, and actually certify that they have the confidence in their ability the same as the originator.

Ms. KUSTER. Great. Thank you.

Mr. Carrier let me turn to you, you have been very helpful this morning. Do you have any concerns about the FDA issuing waivers of the single shared system REMS requirement?

Mr. CARRIER. So I have no concerns. The issue here is that the brand company will slow off the process of a shared REMS. When the brand and the generic each have a REMS, the brand will say, sure, I will get back to you, and then 3 years later it gets back to the generic. So eventually the FDA has to wade in. Thirteen times it has been asked to get in the middle of these. All 13 times, it says, generic, you can go your own way, because the brand has no interest in working with you. And so at the end of the day, the FDA is able to waive the shared REMS requirements.

Still a hundred percent safe, absolutely no concerns there, but it would be a little better to have us not go through that whole song and dance and have the generic be able to enter the market a lot quicker with a completely safe REMS.

Ms. KUSTER. So the 19 times it was always—the brand dragging their feet?

Mr. CARRIER. Yes. That is my sense, that the FDA has—was asked to get involved and the generic has a REMS, it has FDA approval, and still it is not able to be worked out between the two.

Ms. KUSTER. OK. That is very helpful. Thank you.

And then Ms. Kennedy, do you agree that legislation, such as the CREATES Act, is needed to address these kind of gaming tactics?

Ms. KENNEDY. One-hundred percent. We have watched over the last decade as many missed opportunities for generics to get to market and lower the price of healthcare have come and gone. Whatever we can do to help American taxpayers and patients, is incumbent upon us to do that. This is America.

Ms. KUSTER. Do you have a sense of the cost of these types of delay tactics and gaming techniques on healthcare overall, cost to consumers?

Ms. KENNEDY. The costs are amazing. Imagine that we sell a product 50 million doses a month, to people like Kaiser

Permanente, for 6.8 cents a dose. Now, we have to be lean and mean. We don't have the money to do expensive litigation. I am always a fourth or fifth to file. And I am lowering the cost of healthcare and drug products, and I want to do it, and I want to do it with safety and efficacy.

Ms. KUSTER. And what is the impact on multiple filers? When you say you are fourth or fifth into the market, is there still an impact——

Ms. KENNEDY. Yes.

Ms. KUSTER [continuing]. At that point on price?

Ms. KENNEDY. Yes. The first filer typically lowers the cost 25 percent. That is great. But when I get to market, it is 80 to 85 to 90 percent. That is real savings.

Ms. KUSTER. And what is the impact on the quality of that——

Ms. KENNEDY. There is no impact to quality because we are—it is incumbent upon us to prove to the FDA that we are equal or better. And we have to file each and every lot with all complete C of A testing and sterility testing.

Ms. KUSTER. Well, I will just close by saying, it seems clear to me that there are some manufacturers using these REMS requirements as a way to keep competition off the market, and as we have all just heard, that is not the original intention of REMS. And I think we have bipartisan agreement to wade into this and make it a top priority. So thank you. I yield back.

Ms. ESHOO. I thank the gentlewoman.

It is a pleasure to recognize the gentleman from North Carolina, Mr. Hudson.

Mr. HUDSON. Thank you, Chairwoman Eshoo, for holding this important hearing. One of the things I hear constantly from my constituents is their out-of-pocket costs are too high. I think working in a bipartisan way to make generic access to the market as simple as possible is important, not only for our government spend on drug prices but also for our consumers' out-of-pocket cost. Simply put, generics save money.

I do worry, though, we are using generics as a silver bullet for issues facing us with high drug prices. I believe robust protection for innovation needs to remain in place, to continue to nurture the high level of innovation we have seen recently with technology such as CAR–T and CRISPER.

I noticed almost half of my Democratic colleagues on this committee support a policy that allows the Government to strip innovators of their patents through compulsory licensing and allow other manufacturers to produce a generic. Generics need to come to market as soon as provided protections for innovations run out, but not before. Otherwise, we threaten therapies like these new CAR–T drugs which can have an over 80 percent success rate for some cancers. That is a four out of five chance your parent comes home from the hospital after a cancer diagnosis.

To that same point, though, I believe we should reward innovative science, not innovative legal work. I am happy to see the committee consider concepts that will help end legal gamesmanship and support bringing generics to the market, but the process behind this hearing does concern me.

And we don't have the Food and Drug Administration, the agency responsible for implementing these bills, here to testify and give us a chance to ask them questions. As Congress, we should seek the input of the agency that will be regulating this space.

And so, Chairwoman Eshoo, as I have said to you before, I really want to work with you on this issue, want to work with my colleagues across the aisle in a bipartisan way, to advance the concepts we are talking about here today. Could you commit to getting the FDA's written, technical assistance on these bills before we mark up?

Ms. ESHOO. We will.

Mr. HUDSON. Great. I appreciate that. I think that would be very valuable input for us.

And then I appreciate all the witnesses being here today. I have read your testimony. It has been extremely helpful for me in my understanding of this space.

Mr. Karst, I have had concerns with the Purple Book legislation being offered here today. Where—oh, there you are, sir. The transparency is something we all support and we all want, and certainly we have seen the Orange Book requirements since Hatch-Waxman provide benefits to the small-molecule market. Could you provide more detail on how you think the Purple Book legislation could be improved so it could be equally as useful in the statute?

Mr. KARST. Sure. Thank you for the question, Congressman. So—and part of this, I have to say, couched in terms of, it may require a broader change to the BPCIA, but as least as an initial start—and Mr. Kushan and I may disagree to some extent on this—having a list of patents in the Orange—excuse me—in the Purple Book, somewhat akin to the Orange Book, I think, would be helpful for manufacturers.

Now, I recognize Mr. Kushan's concerns that under the current—the proposed bill that the patent information would go in after the first biosimilar challenge and could raise issues about confidentiality, but we can get rid of all that simply by requiring the brand to list all of its patents in the Purple Book, upon licensure of its product. Then potential biosimilar applicants will know the entire patent estate that is out there, that may be shot at them in litigation.

Mr. HUDSON. Great. Well, I appreciate that. That is very helpful.

With that, Mr. Bucshon, do you want the last minute of my time?

Mr. BUCSHON. No, I am good.

Mr. HUDSON. OK. Seeing that, Madam Chairman, I will yield back. Thank you.

Ms. ESHOO. I thank the gentleman.

I think those members that are left are getting—they have an appetite for lunch. Let's see. I would like to recognize the gentlewoman from California, Ms. Barragán, 5 minutes for questioning.

Ms. BARRAGÁN. Thank you, Madam Chairwoman, and thank you to our panel for being here today. It has been great to have conversation on a bipartisan basis that we all want to lower prescription drug prices for Americans. When I have town halls in my district, it is one of the top issues I hear about, and how people have to choose between prescription drugs and rent or groceries. And in a district like mine,—it is very working class—it is so nice to hear,

on the other side, say, hey, we have a common goal to bringing these down. Obviously, we have this hearing today and we see that there is—there is a lot of details, there are some differences, but I am hoping that we can get through them to find a solution.

And, I think back in 1984, when Congress passed the Drug Price Competition and Patent Term Restoration Act which we all know as Hatch-Waxman, the bill kind of laid the ground work for the modern, generic drug, approval system. Now, Congress has worked hard to try to strike this balance between innovation and getting generics to the market as soon as possible. We had the Secretary here yesterday also talking about what we are talking about here today, and it was good to hear from him that he agreed that this delay in getting generics is an issue.

And one aspect of the framework is an incentive for the first generic drug manufacturer to submit their application and come to market, 180 days of market exclusivity. In other words, 180 days during which the FDA could not approve additional generic versions of the same product.

Now, I have been reading, and we have been certainly learning in recent years, that some of the generic drug manufacturers are abusing this reward. They are signing agreements to keep their products off the market longer, or for other business reasons, they do not launch their products as early as can be.

Now, I am the author of one of the pieces of legislation here today, the FAIR Generics Act. I happen to believe that this would help the problem by realigning incentives for generics to come to market sooner.

Mr. Carrier, in your research, have you seen this to be a problem, and could you maybe explain and tell us more about it? You know, why are generic drug manufacturers behaving in this way?

Mr. CARRIER. Absolutely. Thank you for the question and thank you for your support of this incredibly important legislation. The problem is that the brand company is settling with the first filing generic, agreeing not to enter the market for years, and as a result, no one else can enter. As I mentioned before, the Medicare Amendments Act of 2003 was designed to deal with the issue; it has not.

And so the 180-day provision here really needs to be opened up. It is not just the first company to file a Paragraph 4 certification, but it is also a company that is not sued by the brand company. It is the first generic that wins a district court ruling in court, that the patent is invalid or not infringed. So whenever anything about the 180 comes up, the question is, oh, do you need the incentives for the 180? And I would just say, you do not need the full, exclusive 180 just for the first filer. Because right now we have shared exclusivity. You have many generics on the first day. Still tons of generic applications filed. There is an FTC report on authorized generics a decade ago, that found that there is no effect on filing a first-filer application when there is an authorized generic in a small market.

So at the end of the day, we need this. And it is not just me who is saying it. So you go back to the Supreme Court in Actavis, the justices said—Justice Scalia said, Hatch-Waxman made a mistake. You look at what Representative Waxman and Senator Hatch have said. They said it is appalling, the legislation is turned on its head.

The 180 was designed for a certain purpose. It is not being used for that purpose. This is the simplest place to deal with it, not an antitrust law, but with your legislation.

Ms. BARRAGÁN. And earlier on there was some conversation between some of the panelists. Mr. Kushan and Mr. Karst, they had raised concern about the bill. They questioned whether it was an appropriate realignment of market incentives. Is there anything you want to add to kind of respond to those concerns that they raised, and could this legislation be an effective deterrent?

Mr. CARRIER. This legislation would be the most effective deterrent for settlements. And the problem is, a lot of the discussion that we heard this morning was about settlements being good, about entry before the scope of the patent expires. This was all rejected by the Supreme Court in Actavis. Actavis made clear that, sure, settlement is good for the brand and the generic company, but it is outweighed by five public-policy considerations.

The Supreme Court made clear that you don't get to say entries before the end of the patent, so therefore it is procompetitive. That is the scope of the patent test that was rejected because antitrust has to play a crucial role.

And just one final point here, we have heard a lot about the FTC and the number of pay-for-delay settlements going down, but there still are a ton of settlements and there is still a ton of delay. So if you go back through the past 5 years, there have been 771 settlements, 653 of them involved delayed entry. Might not be payment, still delayed entry. Your legislation would solve the problem.

Ms. BARRAGÁN. Thank you, I yield back.

Ms. ESHOO. I thank the gentlewoman.

I now would like to recognize Mr. Carter of Georgia for 5 minutes of questions.

Mr. CARTER. Thank you very much, Madam Chair, and thank all of you for being here. Currently, I am the only pharmacist serving in Congress and have over 30 years of experience in practicing pharmacy. This is a real problem, getting generics to the market. I have seen prices on brand-name drugs drop dramatically whenever generics entered the market. And that is why we need to get it there as soon as we can.

I have so much respect for the pharmaceutical manufacturers who devote and invest in research and development. I have seen nothing short of miracles in my years of practice, that have come out as a result of research and development. However, when a drug is too expensive, and not accessible or affordable, it does no one any good whatsoever. So that is why this is so very important.

I will tell you that I find some of this discussion—in fact, I find much of this discussion more lawyerly than I do pharmacy. So out of all due respect, I am just a little bit taken aback by the legal aspects and how this ever got to this point. But at the same time, that is where we are, so that is what I am going to deal with.

Mr. Davis, I am going to start with you, because quite honestly, you confused me earlier. Mr. Burgess asked you about the CREATES Act, which I think we all agree needs to be done and needs to be done as soon as possible. However, last session, we had an agreement where everyone was on the same page, and now, all of a sudden, this has changed somewhat, where not everyone is on

the same page. And you confused me in your answer to him. Which one do you support, or do you support both of them?

Mr. DAVIS. I believe that the CREATES Act, as has been introduced, we support the CREATES Act——

Mr. CARTER. As has been introduced here, that we are looking at here——

Mr. DAVIS. I will have to go back and will report back to you, Congressman, about any significant differences. I don't believe there are significant differences between what was introduced in the last Congress and this provision——

Mr. CARTER. Well, that is where I get confused at because we are told there are some things that are different. And out of all due respect, if you will just get back with me and let me know, I would appreciate that.

But would you agree—and Ms. Kennedy, you might be able to answer this, too—do you ever do any of the 180-day exclusive, or do you just primarily do after everybody is eligible?

Ms. KENNEDY. We do not have the—we do not have the resources to fight the big litigation, and so, no, we haven't taken a part of the 180-day exclusivity, except for in one case where we are the manufacturer of record for someone who did fight the patent challenges, a company named Apotex. We manufacture for them, a product called Budesonide, a corticosteroid. That is the only time.

Mr. CARTER. OK. Well, as was mentioned, Representative Schrader and I have bipartisan legislation, the BLOCKING Act, that we feel like is good legislation. It is going to make a difference. And that is the key here—how do we make a difference.

You know, of all the committees in Congress, I would submit to you that the Energy and Commerce Committee works in a more bipartisan fashion than any other committee, and I have always been very proud of that. And I continue to be proud of that, and I hope that in this session, we will continue that. That is why this legislation, the BLOCKING Act, that Representative Schrader and I are cosponsoring, is so very important to me, and I want to see us continue with that.

But back to the CREATES, if a—if a generic company asks of a brand manufacturer, I need samples, and they provide it, and there are no other kind of agreements or no other kind of stipulations, should they have the right to still sue? Because if a brand-name manufacturer provides them with everything they have been asked for, shouldn't that be enough? Anyone want to tackle that?

Mr. CARRIER. So——

Mr. CARTER. Anyone want to tackle that?

Mr. CARRIER. Yes, the problem is that they are not getting the samples. So——

Mr. CARTER. No, no, no, no, that is not what I asked, Mr. Carrier. I said that if they got the samples and if we required it as part of the CREATES Act, said you have to give the samples, and if you give the samples, then you have no other excuse. You have 180 days, at that point.That is what I asked.

Mr. CARRIER. So if the brand company is giving the sample, that is fine. The problem is——

Mr. CARTER. OK.

Mr. CARRIER [continuing]. Now they are not.

Mr. CARTER. OK. But if we say that they have complied and they have given the samples, then isn't that a no-brainer? Mr. Davis?

Mr. DAVIS. Just so I understand correctly, Congressman, you are saying that the originator would give the samples——

Mr. CARTER. Right.

Mr. DAVIS [continuing]. To the generic manufacturer?

Mr. CARTER. And there is no other kind of stipulations. If they——

Mr. DAVIS. Would give them? That is actually what we are trying to address here, is——

Mr. CARTER. Right, exactly.

Mr. DAVIS [continuing]. They are not. And often times it comes down to—and I would also suggest that it is not an issue of where generics are asking for them. They are willing to purchase them at fair market price.

Mr. CARTER. OK, I have got 5 seconds left. I just want to mention again that the BLOCKING Act is a perfect example of us working in a bipartisan fashion, and I hope that is what this committee will do.

Also, tomorrow I am going to be introducing more legislation that is more bipartisan, that Mr. Welch and I are—and Mr. Gianforte, we are all cosponsors on this. It is called the Payment Commission Data Act. This will allow MedPAC and MACPAC to get the pricing information from Medicare and from CMS, in order to make recommendations to Congress that we need. So I hope you will be looking out for that as well.

Madam Chair, thank you very much for your indulgence, and I yield back.

Ms. ESHOO. You don't have anything to yield back. It is a term we use around here. I thank the gentleman.

I now would like to recognize a new member of the Energy and Commerce Committee, and we are thrilled that she is high value added to our subcommittee, the gentlewoman from Delaware, Ms. Blunt Rochester.

Ms. BLUNT ROCHESTER. Thank you so much, Madam Chairwoman, and thank you specifically for this important hearing on drug pricing. I also want to thank the panel for your testimony.

I would like to focus our attention on generic drugs and their potential, through market competition, to lower drug prices for American consumers. We have heard today that one of the best ways to reduce drug prices is to ensure generics can come to market as soon as possible, after patent and exclusivity periods expire.

Generic market entry saved $265 billion in 2017, including $82.7 billion for Medicare alone, or $1,952 per enrollee. In fact, according to one estimate, the average drug price decreased by 50 percent in the first year of generic entry, with an 80 percent reduction within 5 years.

I am especially concerned about the impact on patients, when generic drug developers are unable to develop their products due to difficulties with access to samples, as was just stated.

I recently had a constituent write to me about her experience trying to purchase an asthma inhaler she had been using for 20 years. She found that starting in January 2019, the copay for her inhaler had more than doubled. She explored paying out of pocket, but the

costs would have been more than twice her new copay. She looked for a generic but found there was none.

These samples are vital to the development of their applications and without them, they will not be able to come to market. Both the CREATES Act and the FAST Generics Act attempt to deal with this problem.

Mr. Barrueta, do the bills before the committee today constitute meaningful progress in the drug-pricing debate, and from a payer perspective, how do generics and biosimilars help with cost containment?

Mr. BARRUETA. Thank you for the question. I would say, yes, these bills are very important. You know, certainly CREATES, as we said before, needs to get going and get that across the line, and that will be enormously helpful. From a coverage standpoint, generics are crucial. Getting generics on the market in a timely way enables us to continue to provide as comprehensive benefits as we can, so that as we have an orderly process of brand-name drugs becoming eventually generically available, it helps us afford the newer drugs that are coming along as well. So it is absolutely essential to provide stability and access for consumers.

Ms. BLUNT ROCHESTER. I asked the question about cost containment, I actually served as State personnel director in the State of Delaware and trying to contain cost is a pivotal area.

Of the solutions that the committee is considering today, which would you say have the most direct, immediate impact on high drug prices?

Mr. BARRUETA. Again, I think CREATES, getting that done, getting the REMS issue cleared up, I think that will help enormously.

Ms. BLUNT ROCHESTER. And I guess I want to just shift, I know there has been conversation about patents and our patent system. And we know of the high value of patents and also some of the challenges. Can you share with us policies that you think we should be considering in regard to our patent system?

Mr. BARRUETA. That is a—that is a good question and it is a challenging question. You know, the patent laws are crucial. I do—I personally feel that we assume that the law that is in place is something that has been set in stone and shouldn't be revised. We have seen, particularly in the pharmaceutical space, fundamental changes in the economics of the pharmaceutical industry. We have seen incremental extensions in terms—in the 1990s, we saw patents extended from 17 to 20 years. We have seen similar activities around market exclusivities, and it has crept and crept and crept.

What we really want to do is make sure that we are providing innovation—that we are providing incentives to maximize innovation. Maximize innovation, and at the same time, promote access. And there has been a case made for many years that if you over—if you overprotect certain things, if you provide too much of an incentive for something in the short-term, it actually detracts from the incentive to innovate more. So we want to make sure we are achieving the right balance to optimize innovation in the pharmaceutical industry. It is a great industry, we need to make sure that it is very healthy in delivering what is possible for American consumers.

Ms. BLUNT ROCHESTER. And my last question is for Mr. Boutin—did I pronounce that correctly?

Mr. BOUTIN. Sure.

Ms. BLUNT ROCHESTER. You know firsthand how important it is that patients are able to afford their medications, and in your testimony, you mentioned that studies have shown that multiple generic drugs on the market dramatically lower drug prices. Can you speak briefly, or actually follow up, with the entry of multiple generics on the market, how it could benefit patients and how Congress could help increase generic utilization?

Mr. BOUTIN. So quickly, as a patient advocate, I am sick and tired of other stakeholders using patient safety to justify their actions when it harms patients. We support CREATES. We do not see a safety concern. And when you have multiple generics on the market, you see a dramatic reduction in out-of-pocket costs to the patient, their family. It has huge implications for their livelihood.

Ms. BLUNT ROCHESTER. I am out of time. Thank you so much, Madam Chairwoman.

Ms. ESHOO. Thank you.

And now we recognize Mr. Gianforte from Montana for 5 minutes of questioning.

Mr. GIANFORTE. Thank you, Madam Chair, and thank you to the panel for being here. This is a very important topic. We are seeing skyrocketing prescription drug prices that are difficult for Montanans and certainly all Americans.

Just last month, I was talking with a constituent in Great Falls, Montana, who saw her lupus medication increase significantly. It got in the way of her continuing to run her small business and, ultimately, created financial instability for her family. So this is a very important topic we are discussing.

I fully believe that everyone in this chamber is committed to working to get lower drug prices, and I am committed to finding commonsense, bipartisan solutions. To that end, I have been working with my friends on the subcommittee here—Mr. Carter, Mr. Welch—and tomorrow we will be introducing a bill specifically around drug-price transparency, which I think is a step in the right direction.

I look forward to continuing to find innovative and creative ways to solve this problem and working across the aisle to promote them.

I want to start with the CREATES Act, and, Mr. Karst, I have a question if I could. I have two questions, if you could just give me a yes, no, these are easy questions, all right?

Mr. KARST. Yes.

Mr. GIANFORTE. So in 2012, the FTC voted to allow the commission to pursue recovery of ill-gotten gains, more frequently than it had in the past. When pursuing such recovery, the FTC attempts to recapture the profit—key word "profit"—made by the company due to its anticompetitive behavior. Is that correct?

Mr. KARST. I believe so, but I don't know for sure, quite honestly.

Mr. GIANFORTE. Yes, my information says that that is correct, that they were able to go after the profit of a company.

Do you know of any Federal statute that allows for recapture of a company's revenue, rather than profit, derived from anticompetitive behavior?

Mr. KARST. Honestly, I am not a competition attorney, food and drug attorney. That being said, I can't think of any off the top of my head.

Mr. GIANFORTE. OK. And I just want to point out, that essentially this CREATES Act that we are considering would basically put all of the revenue of all drug companies in play for potential lawsuits and capture. And just in my own experience in business, when you have a big pot, it tends to encourage litigation. I have grave concerns about this. You had stated in your testimony, we want to do no harm, and yet creating a target to go after all of the revenues of all drug companies seems to be a step in the wrong direction.

Mr. Kushan, as I read moving to pay-for-delay, as I read the pay-for-delay bill we are considering, I see it would apply retroactively to existing agreements. I have fundamental concerns here with deciding that a behavior that has been lawful for some number of years, and had been the basis of business decisions, would now be open to litigation and lawsuits, particularly because it has been lawful behavior in the past.

This provision seems like it is opening up a can of worms. I am just interested—I am not a lawyer, but I would be interested in your perspective on this. Can you give us a sense of any concerns you may have with the change that we are—is being proposed under this bill?

Mr. KUSHAN. Thank you. So the idea of opening up or voiding one of the settlement agreements after the parties have kind of moved on, you know, is essentially what you are doing, is, you have a patent fight, you come to a settlement, and then the generic launches, the parties have moved on.

When the companies enter into that settlement agreement, the innovator's going to make some calculus about what is appropriate for the market launch. They are going to withhold use of their patents that they might otherwise be able to use, and then you obviously see the product going generic.

We also—I think everybody recognizes on the panel that within a year of the generic going onto the market, you know, the innovator's out. The market share of the innovator goes down to 7 percent or 9 percent. So it is kind of an irrevocable consequence to the innovator. So you can see some very significant disruptions, the business planning of both parties if those settlements fall apart.

Mr. GIANFORTE. In the limited time I have, I want to stay on patents for a second. In our technology business, we were subjected to a couple of dozen, frivolous, patent-related lawsuits that sucked resources away from research in our business. We have heard a lot about a patent abuse. Could you just briefly talk about patent abuses that you have seen, and what we should do about it?

Mr. KUSHAN. Well, obviously, we want to make sure that we don't have patent litigation where the patents are not valid or are not infringed. I mean, you have to—that is the essence of the patent fight. You have to make sure that you are fighting about valid patents, and if you can find a way to avoid burdening courts, burdening the parties with the litigation, you always want to find a solution that drives parties to that outcome.

And I think it is important that we look at these patent scenarios. You really, unfortunately, have to drill into what the parties are doing, and not make kind of a blanket assumption that a patent assertion is bad or good. You have to just look at the merits.

Mr. GIANFORTE. OK. My time is expired, and I yield back, Madam Chair.

Ms. ESHOO. I thank the gentleman. It is a pleasure to recognize the gentleman from Illinois, Mr. Rush.

Mr. RUSH. I want to thank you, Madam Chairwoman, and I am pleased the subcommittee, included my legislation, H.R. 1499, the Protecting Consumer Access to Generic Drugs Act in this important discussion on how best to lower the price of prescription drugs.

No American should be forced to make the choice between paying their bills and buying their pills. For too long, brand-name drug companies have reaped the benefits of limited competition, which forced consumers to pay more for their medications. My bill prohibits the practice of, quote, "pay-for-delay," end of quote, in which brand-name drug companies compensate generic drug manufacturers to delay the entry of cheaper drugs into the market.

I was pleased that a version of this legislation was passed out of this committee during consideration of the Affordable Care Act, but, unfortunately, it was not included in the final bill. So I am proud to continue my fight to stop drug companies from rigging the system in order to take advantage of hardworking Americans, and I am pleased that advancing market competition is a priority for this subcommittee.

Madam Chair, I ask for unanimous consent to submit two letters in support of my bill into the record.

Ms. ESHOO. So ordered.

[The information appears at the conclusion of the hearing.]

Mr. RUSH. Thank you.

My question is for Professor Carrier. In your testimony, you said that brand-name pharmaceuticals who pay generics to delay entry into the market cost consumers $3.5 billion a year. Can you briefly expand on how you reached this $3.5 billion figure, and how we know the high prices are due to the lack of generic competition?

Mr. CARRIER. Sure. So the Federal Trade Commission is the expert on this issue, and they submitted a report a few years ago, where they figured out how much consumers are paying too much each year, and they calculated that it was $3.5 billion a year.

Mr. RUSH. And you concur with that?

Mr. CARRIER. I do.

Mr. RUSH. All right. Mr. Boutin, in your testimony, you said that the National Health Council evaluated almost 200 policy proposals that aim to reduce the cost of healthcare and found that the most expensive policies increased generic drug competition. Can you speak to whether my bill, H.R. 1499, which addresses the presence of pay-for-delay, whether my bill would be expected to increase competition and lower the cost of prescription drugs?

Mr. BOUTIN. Certainly. Competition is the key to driving down costs. There is no question about it. When you look at the patent settlements, there is clearly a spectrum. Clearly some that work well, but—that will actually bring benefit to patients, but there are

clearly some that do not, and we need to actually root them out. So we are supportive. Thank you.

Mr. RUSH. Thank you.

Mr. Barrueta, how do you see this pay-for-delay problems impacting drug prices for your members, and do you think that legislation is necessary to formally deter or outlaw these agreements?

Mr. BARRUETA. I would say, you know, particularly in some of the more expensive products that we are still seeing branded, that are widely available in Europe and elsewhere, whatever is going on, and it does look—I imagine pay-for-delay is some piece of that—I think we should be moving as quickly as we can to make sure that those transactions are appropriately adjudicated and moving it forward so that we are not waiting for an extensive, lengthy, legal process to get that done. So I think this is a step in the right direction.

Mr. RUSH. Thank you, Madam Chair. I yield back.

Ms. ESHOO. I thank the gentleman.

I now would like to recognize the gentleman from Illinois, my friend, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Madam Chairman, it is great to be here. Sorry, I was doing a very simple issue of toxic chemicals upstairs, so I am glad to come down here for a more simpler debate.

So I am going to ask a question to the whole panel. Obviously, there is a big panel here, if you can kind of keep it as short as possible because there are like two or three more I want to try to get to. I understand that there is broad support for the CREATES and FAST Act because of the concern that brand manufacturers game the REM system.

However, we can have a tremendously productive generic market. So I think we can also acknowledge that in the majority of situations, brand manufacturers must be willingly providing samples to generic developers. Does anyone on this panel agree that in most cases, samples necessary for equivalence testing are provided without FDA intervention or litigation?

Anybody? Ms. Kennedy just go across. If you don't want to—you can't—it is not in your purview, that is fine.

Ms. KENNEDY. Could you repeat the—could you repeat the part about FDA intervention? I think you asked, are they being provided, and, no, to my knowledge, the FDA has no part in that. But make sure I heard you——

Mr. SHIMKUS. Are they being provided—does the FDA have to intervene for it to be provided, or does it have to be litigation?

Ms. KENNEDY. I don't think that has fully been determined. I think that is why we are here in this panel because we have got all manner of issues taking place, you know, really disincentivizing us.

Mr. SHIMKUS. OK. Mr. Davis, I think you understand.

Mr. DAVIS. Congressman, thank you for the question. I don't know of and will look at the number of times where there has been a transfer or sale. I know that there have been at least 170 complaints over 55 products where it hasn't happened.

Mr. SHIMKUS. OK. Great.

Mr. Barrueta?

Mr. BARRUETA. That is as good as I can do. So you can keep going.

Mr. SHIMKUS. OK.

Mr. BOUTIN. Same here. I will add that we do hear from companies when they are looking to do comparative tests on their products. They also have difficulty getting samples.

Mr. SHIMKUS. OK.

Mr. KARST. I imagine there are cases where product is provided, but of course you see the numbers FDA has put out and others have been talking about. So it is an issue.

Mr. KUSHAN. I don't have any personal experience in this space. I think one thing that might be helpful is to actually reach out to the different sectors to see what the experiences are, to see how frequent it is.

Mr. SHIMKUS. OK.

Mr. KUSHAN. You know, I hear the examples that are given, and it strikes me that, you know, there are many more situations where there aren't even——

Mr. SHIMKUS. Thank you.

Mr. Carrier?

Mr. CARRIER. I don't know how many times the samples have been provided, but on the website, it says 173 times it has not been provided, and the person who would know best, the Commissioner of the FDA, is trying to do everything about it, showing that it is a real problem.

Mr. SHIMKUS. OK. So then I am going to transfer, following up on Mr. Welch's question—and this is to Mr. Davis—about CREATES versus FAST Generics, does AAM have an opinion on whether revenue or treble damages is a preferable approach, and can you explain why?

Mr. DAVIS. Thank you, Congressman. We do not have a position on that. We just want to make sure that the end product, the legislative vehicle that is moved forward ultimately has a sufficient enforcement mechanism on the back end such that this problem is eliminated.

Mr. SHIMKUS. OK. Going back to you, Mr. Davis, your member companies have been saying their profit margins are getting smaller and smaller given the high cost of litigating patents and to the—to the bitter end. Shouldn't we have—be concerned that limits on settlements will lead to fewer generics challenging brand drug patents and inhibit generic competition and resulting cost savings?

Mr. DAVIS. Thank you, Congressman. It is a concern that the inability, and I think as Ms. Kennedy also testified previously that in the current environment we are in, given the amount of patents that can be filed late stage against an innovator product, that taking away the ability to settle is likely to have the unintended consequence of keeping certain specialty medications on the market longer without competition.

Mr. SHIMKUS. OK. And let me try to get this last one in. Mr. Barrueta, your organization is not just a payer, your organization is also made of healthcare providers. Know that not all drugs are created equal, and some have particular dangers and even deadly effects when not handled properly. When it comes to these exceptional dangerous products do you think that anyone seeking posses-

sion of them should be required to demonstrate to the FDA their ability to properly safeguard the use of these products?

Mr. BARRUETA. Absolutely. And, in fact, we do have a specialty pharmacy operation that has the capacity to comply with REMS' requirements, and sometimes we are not permitted to actually do that because of commercial choices that the manufacturer is making, which actually impairs the ability to get these drugs in an orderly way to our patients. So but the answer to your question is yes.

Mr. SHIMKUS. So this might have been as difficult as toxic chemicals, so I wish I would have been here, but thanks for letting me join at the last minute.

Ms. ESHOO. I thank the gentleman. I now have the pleasure of recognizing the gentlewoman from Illinois, Ms. Kelly.

Ms. KELLY. Three Illinois in a row. Thank you, Madam Chair, and I ask for unanimous consent to submit a letter from Advocate Aurora Health for the hearing record.

Ms. ESHOO. I am sorry, I didn't hear you.

Ms. KELLY. I ask for unanimous consent to enter in——

Ms. ESHOO. So ordered.

[The information appears at the conclusion of the hearing.]

Ms. KELLY. OK. I want to spend some time talking about my bill, the Orange Book Transparency Act. We talked about the Orange Book already, but can you, Mr. Carrier, talk about how the how does the FDA receive the information to put into the Orange Book?

Mr. CARRIER. Sure. So the Orange Book is very useful. As a collection of drugs and patents it puts generic companies on notice. It gives brand companies a lot of benefits in terms of an automatic stay and other benefits to keeping generics at bay. The benefits of this legislation, and thank you for introducing it, is that it makes clear that when a patent is found to be invalid that it is no longer blocking generics from the market.

And so you have an Appellate Court decision, which is basically the final word on the issue. You have a PTAB decision, which is upheld seven out of eight times. It is only 13 percent of the time that it is not upheld by the Federal Circuit. This is important information to have. The brand companies should not be keeping the generic off the market when the patent is no longer any good.

And I am also grateful for the attention to device patents. You look at the EpiPen, you look at insulin pens, and you say, well, why is the price so high? Well, because patents keep getting listed in the Orange Book, and every time the patent is in the Orange Book you keep the generic away, an automatic 30-month stay. There is a lot of power that the brand companies have, so this is very important legislation.

Ms. KELLY. And then what is the FDA's role in maintaining and updating it?

Mr. CARRIER. So the FDA collects this information, but it has said that it only has, quote, a ministerial role. It is not going out and litigating every patent. It is not even going out and looking in the court system to see what has happened. And so sometimes this arises in the courts, and the FDA says we are just ministerial, we mark it in the book, we do nothing more than that, and that is why this legislation is important.

Ms. KELLY. And how can this resource be used as a barrier to generic entry, and how is it abused by companies?

Mr. CARRIER. The problem is that a brand company by listing a patent in the Orange Book forces the generic to do a whole bunch of things. For starters, it is kept off the market for 30 months. Another hurdle is by having to list one of four certifications that you are going to wait for the patent to expire, that you have to challenge the patent saying it is invalid or noninfringed. The brand company can sue the generic even before the generic enters the market. A paragraph 4 certification counts as an act of patent infringement, and so, this is a concern that the brand company can list these patents, and a REMS patent is another example, as well. It is it is not a patent on innovation, it is a patent on how your label is set up where using a computer in a hospital system, this has nothing to do with innovation, this can really harm generics.

Ms. KELLY. And are there any additional policy changes that Congress should be considering to ensure that this list is not being misused by drug manufacturers? And after you answer if anybody else wants to answer is fine.

Mr. CARRIER. So I think focusing on these requirements of a determination by a court, an Appellate Court or a PTAB is very useful, the device patents, and I would add REMS patents to the list, as well. REMS patents have nothing to do with innovation. They should not be listed in the Orange Book.

Mr. KUSHAN. Just on a couple of points, so the PTAB statistics are a little misleading because the trend line is going way down on institution and the increase in instances of reversals. The real problem with anchoring a decision to remove one of the patents from the Orange Book because of a PTAB outcome is that it may get changed, it may get reversed. And that is happening with more frequency, so, you know, from a certainty perspective not just for the innovator but for the generic we don't want to have—one of the essential points of the Hatch-Waxman scheme is that you are going to resolve the patent fight before the generic launches because you don't want to disrupt the marketing of the generic once it is on the market. That is the essence, that is the beauty of the Hatch-Waxman listing scheme. So if you have scenarios where you are going to take a patent out of the Orange Book, launch the generic, then the innovator wins after appeal, you have to pull the generic potentially from the market. That is very disruptive for everybody. And that is why we want to have final outcomes that aren't going to change.

Mr. KARST. And just one point of clarification on Mr. Carrier's testimony, even though the Transparency Act does say that an invalid patent, one that is ruled invalid would have to come out of the Orange Book, the FDA actually will not take it out of the Orange Book if there is a generic applicant who has 180-day exclusivity pending on that. So the agency has to maintain that in order to maintain that first applicant's exclusivity, so just to be clear on that point.

Ms. KELLY. OK. Thank you very much. It is clear to me that we must act to clarify the role of the Orange Book and prevent abuse of this important resource. I look forward to working with stake-

holders to strengthen the role of the Orange Book and close loopholes that allow it to be misused.

I yield back.

Ms. ESHOO. I thank the gentlewoman and thank her for her work for her work product. Let's see, I think is he next? I would like to recognize Mr. Raul Ruiz from the beautiful, magnificent State of California.

Mr. RUIZ. Right on, chairwoman. California is definitely the best State in the Nation.

Mr. Boutin, I want to thank you for joining us today to share your experience representing a coalition that brings together over 160 million patients with chronic diseases and disabilities. I think all members of this committee have heard loud and clear from our constituents that the rising costs of prescription drugs is forcing them to make tough decisions about their healthcare and the care of their family members.

Both in the farm worker community where I grew up in the Coachella Valley, and when I was practicing in the emergency department I saw many families who had to choose between filling their prescriptions and putting food on the table.

In fact, I will tell you a story. I was doing some policy work out in the rural community church and after I left, I noticed one of the participants digging in the trash and I went over and I said, what are you doing? This was before I ran for Congress. And she is like, I am collecting cans. I said, Why. She said I have to pay for my diabetes, my insulin medication, and she said, but don't worry, doctor, I only take half my dose so that I can make it last, and you know what dangers that imposes. So, you know, she rationed—many people ration their medications or delay filling prescriptions all together.

As a doctor I know firsthand the long-term impacts these decisions may have on a patient's health and the healthcare system at large, as well as the immediate risk posed to these patients. Addressing this problem will require us to work together both across the aisle and the country, and it will also require a range of policy solutions. There is no one-size-fits-all.

I am pleased that the committee under your leadership, Congresswoman Eshoo, is examining a number of policies that will help to encourage generic competition. Generic competition is one of the best evidence-based methods to control the cost of drugs. In 2017 the use of generics in Medicaid alone saved $40.6 billion or $568 per patient. Likewise, the use of generics in Medicare saved taxpayers $82.7 billion annually, and it is estimated that expanded generic use would save Medicare even more up to $14 billion, $14 billion per year. While not a silver bullet, generic competition is vital in saving money for taxpayers and out-of-pocket costs for patience.

Mr. Boutin, you noted in your testimony the story of Mackenzie and her struggle with the high out-of-pocket costs and how generic entry has helped to adhere to her medications and stay healthy. The national—my question is how would increased generic competition help your members? And I know that the National Health Council represents a wide array of patients with multiple health conditions, so how would generic competition help your members?

Mr. BOUTIN. So there are 160 million people in the United States living with one or more chronic conditions. Many of them use medications to treat those conditions. Many of them rely on generics. When they have the generics, they are able to dramatically drive down their costs. We have done a great job of expanding access to insurance. We have an incredible number of people who are underinsured who are running into out-of-pocket expenses that are to your point causing them to make decisions about rent, about food, about foregoing that for their family's college or education. The decisions that they are making are becoming huge and the long-term costs are huge.

Mr. RUIZ. How much costs are they bringing home in savings?

Mr. BOUTIN. When they are able to take generics, they can reduce their costs often down to $5 per prescription and sometimes even less.

Mr. RUIZ. From down to from what initial price?

Mr. BOUTIN. It can be anywhere from $60 and sometimes as high as several hundred, and there are some extreme cases where it can be even higher than that.

Mr. RUIZ. And I believe we both would agree that increasing generic and biosimilar competition is only part of the solution to lowering costs, and there are also needs to be more awareness of the availability of these treatment options. So what actions do you think this administration or Congress should be taking to ensure that patients and healthcare providers are aware of available generic and biosimilar medications?

Mr. BOUTIN. Systemwide transparency, so the people have a meaningful opportunity to understand what the options are. We need to provide that transparency in the relationship with their providers and with a pharmacist. So it needs to happen in real time. Technology can enable that.

Mr. RUIZ. Excellent. One thing I was struck by in your testimony was the fact that 43 percent of generic drugs or about 700 have been approved by FDA since January 2017 but still are not available on the market. So what policy solutions does your organization support that would help to reverse this trend?

Mr. BOUTIN. An important issue that needs to be addressed is looking at how we fundamentally pay for generics. We have a process that drives them down to a commodity to drive the price down low, which is good, but if it reaches a point where it creates a disincentive for additional generics to come into the market.

If we were to look at how we could elevate the price only slightly, we are not talking about major tweaks to drive additional entrants into the market and ensure vibrant competition, we would save dramatic amounts of money because people would actually be able to take their medications and not drive long-term costs to the health system.

Mr. RUIZ. Thank you.

Ms. ESHOO. I thank Mr. Ruiz, and it is a pleasure to recognize the gentleman from Maryland, Mr. Sarbanes, my favorite Democratic Greek.

Mr. SARBANES. Thank you very much. I appreciate that. I want to thank the panel for your testimony. Mr. Carrier, I wanted to talk to you a little bit more about the pay-for-delay deals. We have

had quite a bit of discussion about it so far today. In full disclosure I strongly support, as you probably are surprised to hear, Congressman Rush's proposal.

As we have heard a number of times according to the FTC these agreements were estimated to cost consumers, between 2010 and 2020, about three and a half billion dollars in increased drug costs, and you have spoken to that today. And the Supreme Court did in the Actavis case note that these types of agreements are anticompetitive, but they still happen. They still continue to occur. We know that there is a lot of time and energy that has to be expended by the FTC in conducting a review, and in a sense, they are doing these reviews from scratch without being able to operate with a presumption that is leaning against them based on their anticompetitive nature. So it is really a kind of case-by-case thing, which takes a lot of the commission's time and focus.

Can you just describe a little bit why the Actavis decision may or may not have been sufficient in terms of discouraging these pay-for-delay settlements, why we are at a point where they continue to go on with the anticompetitive impact that it has?

Mr. CARRIER. They continue to go on because brand companies and settling generic companies are dancing together to go back to the analogy that started this hearing. It is in the interest of the brand and the settling generic to agree not to enter the market with a generic maybe getting more money than it would have gotten by entering the market.

The Supreme Court made clear that these agreements could have anticompetitive effects. The Supreme Court rejected a lot of the arguments we have heard this morning about settlements being good and entry before the end of the patent, that was all rejected by Actavis, and it has no reason coming up right now.

Nonetheless, there is a lot of play in the joints, and there is reason for brand companies to try to do everything possible to sow ambiguity. And sometimes you see courts getting it wrong. Sometimes courts focus on the patent. Sometimes courts say risk aversion is a good thing, entry before the end of the patent is a good thing, and so courts are still struggling with these issues and making clear that the agreements are illegal would be very helpful.

And if I could just say one thing on retroactivity because that has come up a lot, as well, and so the bill is absolutely clear that there is no penalty until after the date of the agreement, and the only retroactive part goes back to June 17, 2013, the date of Actavis.

So it is only retroactive if you are going to ignore the Supreme Court. The Supreme Court said it was illegal to enter into pay-for-delay settlements, and so, there is complete notice that the parties then would be violating the law.

Mr. SARBANES. Thank you. And the value of creating a kind of bright line standard here makes a lot of sense to me. Obviously, it would put the agency in a much stronger position because it would come to these cases and these pay-for-delay deals with a presumption that they are anticompetitive, they are illegal and would be able to take the kind of steps of enforcement and oversight that that would provide.

And I know that—I know that there have been some pretty stark examples here. Humira entered into eight different patent settlement agreements. I was very happy to work on a Biosimilars Competition Act that we were able to get passed into law last year as you may know. Before that they weren't even required to report these kinds of settlements to the FTC.

But I think what Congressman Rush has proposed makes perfect sense in the wake of the Actavis case. It makes perfect sense when you look at the burden that it places on the FTC to have to do this review on a case-by-case basis, and what the new authority that they would come with if we were to put Congressman Rush's bill in place.

So I very strongly support it, and I appreciate the testimony that you have offered today, which certainly provides further justification for the proposal.

And with that I would yield back my time to the gentlewoman.

Ms. ESHOO. I thank the gentleman and especially for his patience because this has been a long hearing. And speaking of patience the tenacious, the patient gentlewoman from Illinois, Ms. Schakowsky, for 5 minutes of questioning.

Ms. SCHAKOWSKY. I want to thank you again, Madam Chair. I am waiving on to this subcommittee, and you have been very generous in that, and I appreciate it so much.

In the 114th Congress I first introduced the FAIR Drug Pricing Act, which would require pharmaceutical manufacturers to notify HHS and submit a transparency and justification report 30 days before they increase the price of certain drugs by more than 10 percent or by more than 25 percent over 3 years.

Though the bill will not prohibit manufacturers from increasing prices it will for the first time give taxpayer notice of price increases and bring basic transparency to the makers of prescription drugs. And so I reintroduced this legislation in the last Congress, and I plan to do so in the coming weeks.

Mr. Barrueta, do you believe that this very basic form of transparency could ultimately lower prescription drug prices for Americans?

Mr. BARRUETA. I think absolutely. We have been eagerly pursuing legislation of this nature at the State level in a number of States in which we operate, and having I think a national law would significantly encourage manufacturers to at least know that the people will know how their pricing and why they are claiming to price it. And——

Ms. SCHAKOWSKY. I feel like we have been beat over the head so many times by, oh, we have to charge this much because of research and development, and we know nothing about how much the drug actually costs to make. I hope we can pass that.

Under current law brand pharmaceutical manufacturers are able to extend the length of the patent protection on their brand drug products by introducing a reformulated version of the same medication, which then receives extended exclusivity. This practice commonly referred to as evergreening often involves really no change to the drug's clinical effectiveness, and the extended patent protection can often be achieved, for example, by simply reformulating an immediate-release product into an extended-release pill.

This practice of taking the same medication and changing its delivery is estimated to cost Medicare—the Medicare program approximately a billion dollars per year in additional drug costs.

Mr. Carrier, I wanted to ask you, given that evergreening incentivizes brand drug manufacturers to intentionally delay, we talked a bit about pay-for-delay, but this is another way to get at it, would—so let me get your comment on that. What are the policy changes that you believe should be considered?

Mr. CARRIER. I think that Congress can do two things. One is to give the FTC power to investigate the phenomenon. So usually what happens in the courts is it falls into one of two situations. One is called the hard switch, the other is called the soft switch. With the hard switch the brand company is pulling the old drug off the market, and the courts say oh, that is bad because you are going from two down to one. With a soft switch they leave the old drug the market, and courts say oh, that is good because you have two drugs to choose from.

The problem is that these are unique markets, they are characterized by a price disconnect where the decisionmaker is different than the buyer, and so the FTC should look into this conduct to show that soft switches can be anticompetitive, as well.

And the only other thing I would say is to think about offering a test that I have offered called the no economic sense test. Rather than the rule of reason, let's give the brand company every benefit of the doubt. If there is any reason at all for your switch, then we will allow it. We just can't allow it where the only reason is to keep the generic off the market.

Namenda, the brand company pulls a $1.5 billion drug off the market. Suboxone, the brand company disparages its own product. Why does it do this? The only reason is to hurt the generic. That is not allowed. That should be an antitrust violation. Congress can do something about that.

Ms. SCHAKOWSKY. Well, actually, my subcommittee deals with the FTC and those kinds of questions, and so I am hoping we can deal with evergreening in that way. All right. I want to say that I do support all the bills that have been suggested today, and I really look forward to working with you, Madam Chair. Thank you. Bye. I yield back, not bye.

Ms. ESHOO. I thank you, and good-bye. I will see you on the floor. I thank the gentlewoman.

Let me offer my sincerest thanks to each one of you. I notice that you were looking at your watch—oh, who is back? Oh, I am sorry. The gentleman from Florida, Mr. Soto, last but not least.

Mr. SOTO. I will be brief, Madam Chair. I know——

Ms. ESHOO. That is music to our ears.

Mr. SOTO. We are getting to voting soon. You know, we live in an amazing time where diseases and conditions that would have easily killed our grandparents or great grandparents or parents are now things that people readily survive from because of the great research done in the United States, and in countries, only a few in Europe and Japan and other places that are really changing the world. And I believe we have to bend the arc of prescription prices without breaking the innovation arc in the process, so it really is quite the balance.

I want to start out by just talking a little bit about some constituents who have been concerned about diabetes medication. Jeff Dunlop from my district said imagine being extorted into paying a 15 to $20 fee every day of your life in order to stay alive, welcome to Type 1 diabetes. Obviously, there is a frustration on behalf of patients who are now taking advantage of these lifesaving drugs.

So I just want to hear from each of you from this specific scenario of diabetes medication, whether you think making generics more accessible and competitive would be helpful in this scenario and why, and we will start from the left.

Ms. KENNEDY. I am not in the diabetic space, but I am in a space very near and dear to that one, and that is COPD. Often times both—patients have both problems. I would suggest that everything we have discussed here today to involve more competition and let Americans do what Americans do, which is appreciate capitalism gets us to where we need to be, and I support all of the things that have been introduced today that really upholds that spirit of competition.

Mr. SOTO. And Mr. Davis?

Mr. DAVIS. Congressman, thank you for the question. I think the story you shared about your constituent just reinforces how vital it is, and I said earlier that issues related to insulin are sort of the perfect storm of what is not working. Whether it is the rebate scheme, whether it is late staging patenting or this regulatory challenge that we have heading into March of 2020, they are all issues that need to be resolved so we can get biosimilars to market.

Mr. SOTO. Mr. Barrueta?

Mr. BARRUETA. Absolutely, completely agree. It is one of the biggest problems that we have and that is a big reason why we are here is to start working on exactly insulin.

Mr. SOTO. Mr. Boutin?

Mr. BOUTIN. Agreed and systemwide transparency so we understand how products flow and how they are priced so that we can effectively get the most effective product that works and the most effective in terms of cost to patients.

Mr. SOTO. Thanks. Mr. Karst?

Mr. KARST. If you agree that greater competition yields lower prices absolutely, which is why it is important to preserve 180-day exclusivity, which is why I would really oppose the BLOCKING Act.

Mr. SOTO. Mr. Kushan?

Mr. KUSHAN. So certainly, everybody supports a generic drug's role in driving prices down. I think what we all hope for is the technology that we are living with today gives you the solution that you don't need to take that drug every day. We are seeing cures for diseases that were uncurable before delivered by biotech and these amazing innovations.

So we want to make sure that we drive both solutions. We want the solutions that solve the bigger problem, which is having to take drugs every day, and that—now we are living in an era, which is amazing that we can get cures to things that nobody could have imagined before.

Mr. SOTO. Thanks. And Mr. Carrier?

Mr. CARRIER. So first focus on PBMs and formularies and what products appear on the formulary, and second, deal with the patent issue.

So IMAC has put out a report that shows that the Lantus insulin injector pen has 74 patents, 95 percent of which were introduced after the device entered the market. And so the Orange Book Transparency Act would go a long way towards dealing with this in focusing on devices being listed in the Orange Book.

Mr. SOTO. Thank you. I appreciate it. I know Mr. Dunlap back in my district appreciates your responses, as well, and I yield back.

Ms. ESHOO. I thank the gentleman.

Let me once again thank all the witnesses. Legislative hearings are very important, and while this was long, each one of you are really value added to this because, number one, all of your experience and your knowledge no one can say to any one of you you don't know what you are talking about, but it takes it a step further in terms of where you were hesitant, what you support, the recommendations that you were making to us on the seven bills in order to improve them.

So I can't thank you enough. This is a worthy experience on behalf of the American people, and I would also like to add that I hope from where you sit that Members from both sides of the aisle are a source of inspiration to you for the work that they are doing together in order to produce legislative products that are going to, again, be worthy of the American people. I think that we are a can-do committee, and that we can certainly bring the costs down, close the loopholes, protect the innovation.

The United States of America is the leader in the world. You can't—no one can point to any other country that produces the—you know, lifesaving and cures turning death sentences into chronic conditions, so I think that we can lower prices, protect what I just described and obviously keep competition in the system because that always brings down prices. So I hope that we have been a little bit of a source of inspiration to you.

I have a homework assignment for you though, and I think every member was asking for this. You made some very important recommendations of how we could improve the bills. I ask that each one of you send us your bullet points. It can be on one bill. It can be on all seven. It can be four, whatever it is, but I really want to—and all the Members do want to review that. We don't want it to be lost, and I think that it would be, again, very good ideas.

Does the gentleman from Indiana want to say anything? No? All right.

At this point I am asking for unanimous consent to submit the following documents for the record. Bear with me, it is a long list. I will read as fast as I can. Letter of support from AARP for the CREATES Act and the Protection Consumer Access to Generic Drugs Act of 2019, a letter of support from AFSCME.

Mr. GRIFFITH. Madam Chair, I move that we waive the reading of the documents and accept them without objection.

Ms. ESHOO. I thank the gentleman.

Ms. ESHOO. With that I think that we will adjourn now. It is lunchtime. Thank you everyone.

[Whereupon, at 1:35 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. JEFF DUNCAN

Madam Chairwoman, thank you for giving me the opportunity to be here today. I would like to use my time to introduce the President, CEO and owner of Nephron Pharmaceuticals, and my good friend and fellow South Carolinian, Ms. Lou Kennedy. Nephron Pharmaceuticals moved their headquarters to South Carolina in 2017, and employees over 600 people locally, all with a variety of skill sets. It is important to note that Lou is strongly supportive of our local veterans. Nephron hires a significant amount of veterans to the corporation, as they're already primed to follow a chain of command in the work environment. Lou is also supportive of the University of South Carolina, where Nephron recently established the Kennedy Pharmacy Innovation Center in conjunction with the University's Pharmacy School.

Lou is very active outside of the corporation, where she serves on a number of different business and civic boards including the South Carolina Chamber of Commerce. I am so proud of the work that Lou is doing for our home state and know that she will make South Carolina proud testifying before this committee today. Thank you, Lou, and thank you Madam Chairwoman.

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116TH CONGRESS
1ST SESSION

H. R. 938

To amend the Federal Food, Drug, and Cosmetic Act, with respect to eligibility for approval of a subsequent generic drug, to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 31, 2019

Mr. SCHRADER (for himself and Mr. CARTER of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act, with respect to eligibility for approval of a subsequent generic drug, to remove the barrier to that approval posed by the 180-day exclusivity period afforded to a first generic applicant that has not yet received final approval, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2019" or the "BLOCKING Act of 2019".

SEC. 2. CHANGE CONDITIONS OF FIRST GENERIC EXCLUSIVITY TO SPUR ACCESS AND COMPETITION.

Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amended—

(1) in subclause (I), by striking "180 days after" and all that follows through the period at the end and inserting the following: "180 days after the earlier of—

"(aa) the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant; or

"(bb) the applicable date specified in subclause (III).''; and

(2) by adding at the end the following new subclause:

"(III) APPLICABLE DATE.—The applicable date specified in this subclause, with respect to an application for a drug described in subclause (I), is the date on which each of the following conditions is first met:

"(aa) The approval of such an application could be made effective, but for the eligibility of a first appli-

cant for 180-day exclusivity under this clause.

"(bb) At least 30 months have passed since the date of submission of an application for the drug by at least one first applicant.

"(cc) Approval of an application for the drug submitted by at least one first applicant is not precluded under clause (iii).

"(dd) No application for the drug submitted by any first applicant is approved at the time the conditions under items (aa), (bb), and (cc) are all met, regardless of whether such an application is subsequently approved.".

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116TH CONGRESS
1ST SESSION

H. R. 965

To promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 5, 2019

Mr. CICILLINE (for himself, Mr. SENSENBRENNER, Mr. NADLER, Mr. COLLINS of Georgia, Mr. WELCH, and Mr. MCKINLEY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Creating and Restoring Equal Access to Equivalent Samples Act of 2019" or the "CREATES Act of 2019".

SEC. 2. FINDINGS.

Congress finds the following:

(1) It is the policy of the United States to promote competition in the market for drugs and biological products by facilitating the timely entry of low-cost generic and biosimilar versions of those drugs and biological products.

(2) Since their enactment in 1984 and 2010, respectively, the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417; 98 Stat. 1585) and the Biologics Price Competition and Innovation Act of 2009 (subtitle A of title VII of Public Law 111–148; 124 Stat. 804), have provided pathways for making lower-cost versions of previously approved drugs and previously licensed biological products available to the people of the United States in a timely manner, thereby lowering overall prescription drug costs for patients and taxpayers by billions of dollars each year.

(3) In order for these pathways to function as intended, developers of generic drugs and biosimilar biological products (referred to in this section as ''generic product developers'') must be able to obtain quantities of the reference listed drug or biological product with which the generic drug or biosimilar biological product is intended to compete (referred to

in this section as a "covered product") for purposes of supporting an application for approval by the Food and Drug Administration, including for testing to show that—

(A) a prospective generic drug is bioequivalent to the covered product in accordance with subsection (j) of section 505 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355), or meets the requirements for approval of an application submitted under subsection (b)(2) of that section; or

(B) a prospective biosimilar biological product is biosimilar to or interchangeable with its reference biological product under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as applicable.

(4) For drugs and biological products that are subject to a risk evaluation and mitigation strategy, another essential component in the creation of low-cost generic and biosimilar versions of covered products is the ability of generic product developers to join the manufacturer of the covered product (referred to in this section as the "license holder") in a single, shared system of elements to assure safe use and supporting agreements as required by sec-

tion 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1), or secure a variance therefrom.

(5) Contrary to the policy of the United States to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, certain license holders are preventing generic product developers from obtaining quantities of the covered product necessary for the generic product developer to support an application for approval by the Food and Drug Administration, including testing to show bioequivalence, biosimilarity, or interchangeability to the covered product, in some instances based on the justification that the covered product is subject to a risk evaluation and mitigation strategy with elements to assure safe use under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1).

(6) The Director of the Center for Drug Evaluation and Research of the Food and Drug Administration has testified that some manufacturers of covered products have used risk evaluation and mitigation strategies and distribution restrictions adopted by the manufacturer on their own behalf as reasons

to not sell quantities of a covered product to generic product developers, causing barriers and delays in getting generic products on the market. The Food and Drug Administration has reported receiving significant numbers of inquiries from generic product developers who were unable to obtain samples of covered products to conduct necessary testing and otherwise meet requirements for approval of generic drugs.

(7) In 2018, the Acting Chairman of the Federal Trade Commission testified that the Federal Trade Commission continues to be very concerned about potential abuses by manufacturers of brand drugs of risk evaluation and mitigation strategies or other closed distribution systems to impede generic competition.

(8) Also contrary to the policy of the United States to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, certain license holders are impeding the prompt negotiation and development on commercially reasonable terms of a single, shared system of elements to assure safe use, which may be necessary for the ge-

neric product developer to gain approval for its drug or licensing for its biological product.

(9) While the antitrust laws may address the refusal by some license holders to provide quantities of a covered product to a generic product developer, a more tailored legal pathway would help ensure that generic product developers can obtain necessary quantities of a covered product in a timely way for purposes of developing a generic drug or biosimilar biological product, facilitating competition in the marketplace for drugs and biological products.

(10) The antitrust laws may address actions by license holders who impede the prompt negotiation and development of a single, shared system of elements to assure safe use, and the Food and Drug Administration has some authority to waive the requirement of a single, shared system. Clearer regulatory authority to approve different systems that meet the statutory requirements to ensure patient safety, however, would limit the effectiveness of bad faith negotiations over single, shared systems to delay generic approval. At the same time, clearer regulatory authority would ensure all systems protect patient safety.

SEC. 3. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

(1) the term "commercially reasonable, market-based terms" means—

(A) a nondiscriminatory price for the sale of the covered product at or below, but not greater than, the most recent wholesale acquisition cost for the drug, as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B));

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

(C) no additional conditions are imposed on the sale of the covered product;

(2) the term "covered product"—

(A) means—

(i) any drug approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to support approval of an application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, or otherwise meet the requirements for approval under either such section, any product, including any device, that is marketed or intended for use with such a drug or biological product; and

(B) does not include any drug or biological product that appears on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), unless the shortage will not be promptly resolved—

(i) as demonstrated by the fact that the drug or biological product has been in shortage for more than 6 months; or

(ii) as otherwise determined by the Secretary;

(3) the term "device" has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(4) the term "eligible product developer" means a person that seeks to develop a product for approval pursuant to an application for approval under subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or for licensing pursuant to an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k));

(5) the term "license holder" means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the holder of a license under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a covered product;

(6) the term "REMS" means a risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(7) the term "REMS with ETASU" means a REMS that contains elements to assure safe use

under section 505–1(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f));

(8) the term "Secretary" means the Secretary of Health and Human Services;

(9) the term "single, shared system of elements to assure safe use" means a single, shared system of elements to assure safe use under section 505–1(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)); and

(10) the term "sufficient quantities" means an amount of a covered product that allows the eligible product developer to—

(A) conduct testing to support an application under—

(i) subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

(ii) section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)); and

(B) fulfill any regulatory requirements relating to approval of such an application.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

(1) IN GENERAL.—An eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

(I) the covered product is not subject to a REMS with ETASU; or

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of

the covered product authorization to the license holder;

(ii) that, as of the date on which the civil action is filed, the product developer has not obtained sufficient quantities of the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has requested to purchase sufficient quantities of the covered product from the license holder; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

(II) for a covered product that is subject to a REMS with ETASU, by 31 days after the later of—

(aa) the date on which the license holder received the request for the covered product; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.

(ii) AUTHORIZATION.—Not later than 120 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

(I) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

(II) development and testing that involves human clinical trials, if the eligible product developer has—

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

(BB) otherwise satisfied the Secretary that such protections will be provided; and

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered

product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

(3) AFFIRMATIVE DEFENSE.—In a civil action brought under paragraph (1), it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence—

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms; or

(B) that—

(i) the license holder sells the covered product through agents, distributors, or wholesalers;

(ii) the license holder has placed no restrictions, explicit or implicit, on its agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder.

(4) REMEDIES.—

(A) IN GENERAL.—If an eligible product developer prevails in a civil action brought under paragraph (1), the court shall—

(i) order the license holder to provide to the eligible product developer without delay sufficient quantities of the covered product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney's fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide other eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

(II) that the license holder failed to comply with an order issued under clause (i).

(B) MAXIMUM MONETARY AMOUNT.—A monetary amount awarded under subparagraph (A)(iii) shall not be greater than the revenue that the license holder earned on the covered product during the period—

(i) beginning on—

(I) for a covered product that is not subject to a REMS with ETASU, the date that is 31 days after the date on which the license holder received the request; or

(II) for a covered product that is subject to a REMS with ETASU, the date that is 31 days after the later of—

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

(C) AVOIDANCE OF DELAY.—The court may issue an order under subparagraph (A)(i) before conducting further proceedings that may be necessary to determine whether the eligible

product developer is entitled to an award under clause (ii) or (iii) of subparagraph (A), or the amount of any such award.

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

(d) NO VIOLATION OF REMS.—The provision of samples of a drug pursuant to an authorization under subsection (b)(2)(B) shall not be considered a violation of the requirements of any risk evaluation and mitigation strategy that may be in place under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) for such drug.

(e) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term ''antitrust laws''—

(A) has the meaning given the term in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12); and

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

SEC. 4. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

Section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1) is amended—

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking "or" after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting "; or"; and

(C) by adding at the end the following:

"(iii) accommodate different, comparable approved risk evaluation and mitigation strategies for a drug that is the subject of an application under section 505(j), and the applicable listed drug.";

(2) in subsection (i)(1), by striking subparagraph (C) and inserting the following:

"(C)(i) Elements to assure safe use, if required under subsection (f) for the listed drug, which, subject to clause (ii), for a drug that is the subject of an application under section 505(j) may use—

"(I) a single, shared system with the listed drug under subsection (f); or

"(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

"(ii) The Secretary may require a drug that is the subject of an application under section 505(j) and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f)."; and

(3) by adding at the end the following:

"(l) SEPARATE REMS.—When used in this section, the terms "different, comparable aspect of the elements to assure safe use" or "different, comparable approved risk evaluation and mitigation strategies" means a risk evaluation and mitigation strategy for a drug that is the subject of an application under section 505(j) that uses different methods or operational means than the strategy

required under subsection (a) for the applicable listed drug, or other application under section 505(j) with the same such listed drug, but achieves the same level of safety as such strategy.''.

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116TH CONGRESS
1ST SESSION

H. R. 985

To amend the Federal Food, Drug, and Cosmetic Act to ensure that eligible product developers have competitive access to approved drugs and licensed biological products, so as to enable eligible product developers to develop and test new products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 5, 2019

Mr. WELCH (for himself, Mr. MCKINLEY, and Mr. CICILLINE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure that eligible product developers have competitive access to approved drugs and licensed biological products, so as to enable eligible product developers to develop and test new products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Fair Access for Safe and Timely Generics Act of 2019" or the "FAST Generics Act of 2019".

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Reference product license or approval holders are restricting competitive access to reference products by sponsors seeking to develop drugs, generic drugs, and biosimilars under section 505(b)(2) or 505(j) of the Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2) and 355(j)) and under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)). These restrictions are deterring and delaying development of drugs, generic drugs, and biosimilars by extending lawful patent-based monopolies beyond their lawful patent life.

(2) The enforcement provisions set forth in section 505–1(f)(8) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)(8)) have not been sufficient to prevent anti-competitive practices that interfere with access to reference products which is necessary for the timely development of affordable drugs, generic drugs, and biosimilars.

(3) There is not a regulatory structure in place that is sufficient to deter or remedy the anti-competitive harm that results when—

(A) access to reference products is restricted to sponsors developing drugs, generic drugs, or biosimilars in accordance with section

505(b)(2) or 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2) or 355(j)), and section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), respectively; or

(B) license holders impede the prompt negotiation and development of a single, shared system of elements to assure safe use and supporting agreements under section 505–1(i)(1)(B) of such Act (21 U.S.C. 355–1(i)(1)(B)), on commercially reasonable terms.

(4) Requiring license holders to comply with requirements for competitive access to their products, and for the negotiation and development of single, shared systems of elements to assure safe use under section 505–1(i)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(i)(1)(B)), and subjecting license holders to liability for failing to do so, will not impose obligations on the courts that they cannot adequately and reasonably adjudicate.

SEC. 3. COMPETITIVE ACCESS TO COVERED PRODUCTS FOR DEVELOPMENT PURPOSES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-

ed by inserting after section 505–1 of such Act (21 U.S.C. 355–1) the following new section:

"SEC. 505–2. COMPETITIVE ACCESS TO COVERED PRODUCTS FOR DEVELOPMENT PURPOSES.

"(a) DEFINITIONS.—In this section:

"(1) COVERED PRODUCT.—The term 'covered product'—

"(A) means—

"(i) any drug approved under section 505 or biological product licensed under section 351 of the Public Health Service Act;

"(ii) any combination thereof; or

"(iii) when reasonably necessary to demonstrate sameness, biosimilarity, or interchangeability for purposes of this section, section 505, or section 351 of the Public Health Service Act (as applicable), any product, including any device, that is marketed or intended for use with such drug or biological product; and

"(B) excludes any drug or biological product which the Secretary has determined to be currently in shortage and that appears on the drug shortage list in effect under section 506E,

unless the shortage will not be promptly resolved—

"(i) as demonstrated by the fact that the drug or biological product has been in shortage for more than 6 months; or

"(ii) as otherwise determined by the Secretary.

"(2) ELIGIBLE PRODUCT DEVELOPER.—The term 'eligible product developer' means a person that seeks to develop a product for approval pursuant to an application under section 505(b)(2) or 505(j) or for licensing pursuant to an application under section 351(k) of the Public Health Service Act.

"(3) LICENSE HOLDER.—The term 'license holder' means the holder of an application approved under section 505(b) or section 505(j) of this Act or under section 351 of the Public Health Service Act for a covered product (including the holder's agents, wholesalers, distributors, assigns, corporate affiliates, and contractors).

"(4) REMS.—The term 'REMS' means a risk evaluation and mitigation strategy under section 505–1.

"(5) REMS PRODUCT.—The term 'REMS product' means a covered product that—

"(A) is subject to a risk evaluation and mitigation strategy under section 505–1; or

"(B) is deemed under section 909(b) of the Food and Drug Administration Amendments Act of 2007 to have in effect an approved risk evaluation and mitigation strategy under section 505–1.

"(6) REMS IMPACTING PRODUCT DISTRIBUTION.—The term 'REMS impacting product distribution' means a REMS that contains elements to assure safe use that impact the distribution of the product subject to the REMS.

"(b) COMPETITIVE ACCESS TO COVERED PRODUCTS AS A CONDITION ON APPROVAL OR LICENSING.—As a condition of approval or licensure, or continuation or renewal of approval or licensure, of a covered product under section 505 of this Act or section 351 of the Public Health Service Act, respectively, the Secretary shall require that the covered product's license holder not construe or apply any condition or restriction relating to the sale, resale, or distribution of the covered product, including any condition or restriction adopted, imposed, or enforced as an aspect of a risk evaluation and mitigation strategy, in a way that restricts or has the effect of restricting the supply

of such covered product to an eligible product developer for development or testing purposes.

"(c) COMPETITIVE ACCESS FOR DEVELOPMENT PURPOSES TO PRODUCTS WITH REMS IMPACTING PRODUCT DISTRIBUTION.—With respect to a product subject to a REMS impacting product distribution, no aspect of such a REMS shall be construed or applied by the REMS product's license holder in a way that prohibits or restricts the supply, at commercially reasonable, market-based prices, of such REMS product from the REMS product's license holder to an eligible product developer with an applicable individual covered product authorization obtained pursuant to subsection (e) for development and testing purposes.

"(d) SINGLE, SHARED SYSTEM OF ELEMENTS TO ASSURE SAFE USE.—Where an eligible product developer seeks approval of an application under 505(j) referencing a REMS product whose REMS includes elements to assure safe use—

"(1) no license holder shall take any step that impedes—

"(A) the prompt development on commercially reasonable terms of a single, shared system of elements to assure safe use under section 505–1; or

"(B) the prompt entry on commercially reasonable terms of an eligible product developer into a previously approved system of elements to assure safe use; and

"(2) license holders shall negotiate in good faith towards the prompt development of (or entry into) a single, shared system of elements to assure safe use under section 505–1(i) on commercially reasonable terms.

"(e) PROCEDURES FOR OBTAINING ACCESS TO COVERED PRODUCTS.—

"(1) COMPETITIVE ACCESS TO PRODUCTS NOT SUBJECT TO REMS IMPACTING PRODUCT DISTRIBUTION.—Notwithstanding any other provision of law, a license holder that receives a request from an eligible product developer or its agent for sufficient supplies of a covered product (that is not subject to a REMS impacting product distribution) to conduct testing necessary to support an application under section 505(b)(2) or 505(j) or under section 351(k) of the Public Health Service Act (or otherwise meet the requirements for approval of such an application) shall provide to the eligible product developer or its agent the quantity requested within 30 days of receipt of the request at a nondiscriminatory,

commercially reasonable, market-based price for which such covered product has been previously sold by the license holder to third parties in the open market.

"(2) COMPETITIVE ACCESS TO PRODUCTS SUBJECT TO REMS IMPACTING PRODUCT DISTRIBUTION: INDIVIDUAL COVERED PRODUCT AUTHORIZATION.—Any eligible product developer may seek an authorization to obtain an individual covered product subject to a REMS impacting product distribution for development and testing purposes by making a written request to the Secretary. Within 120 days of receiving such a request, the Secretary shall, by written notice, issue such authorization for purposes of—

"(A) development and testing that does not involve human clinical trials, if the eligible product developer has agreed to comply with any conditions the Secretary determines necessary; or

"(B) development and testing that involves human clinical trials if the eligible product developer has—

"(i) submitted a protocol for testing that includes protections that will provide

an assurance of safety comparable to the assurance of safety provided by any distribution restrictions governing the approval or licensure of the covered product; or

"(ii) otherwise satisfied the Secretary that such protections will be provided.

"(3)(A) PROCESS FOR OBTAINING PRODUCT PURSUANT TO AN AUTHORIZATION.—

"(i) An eligible product developer shall be entitled to obtain, from the license holder of a covered product subject to a REMS impacting distribution, sufficient quantities of the covered product for purposes of development and testing necessary to support an application under section 505(b)(2) or 505(j) or under section 351(k) of the Public Health Service Act, or otherwise meet the requirements for approval of such application, if the eligible product developer has obtained an applicable authorization under paragraph (2).

"(ii) Each license holder shall publicly designate at least one wholesaler or specialty distributor to receive and fulfill requests for cov-

ered products submitted pursuant to paragraph (1) or clause (i) of this paragraph.

"(iii) An eligible product developer shall initiate its acquisition of a covered product under clause (i) by providing or having its agent provide a written request for specific quantities of such covered product to the license holder.

"(B) REQUEST CONTENTS AND RESPONSE.—A request under subparagraph (A)(iii) shall include a statement regarding the quantity of covered product sought for development or testing purposes, and state that the eligible product developer has an authorization under paragraph (2) to obtain the specific covered product. Within 30 days of receiving such a request, the wholesaler or specialty distributor shall provide the requested quantity of the covered product at a nondiscriminatory, commercially reasonable, market-based price for which such covered product has been previously sold by the license holder to third parties in the open market.

"(C) DISCLOSURE OF INFORMATION BY WHOLESALERS AND SPECIALTY DISTRIBUTORS.—In the event that a request is made to a wholesaler or specialty distributor under this paragraph, the

wholesaler or specialty distributor shall not disclose to the license holder of the covered product involved the identity of the eligible product developer, but may disclose to such license holder—

"(i) the fact that a request has been made;

"(ii) the dates on which the request was made and fulfilled;

"(iii) the commercial terms on which the request was fulfilled; and

"(iv) the quantity of the covered product furnished by the wholesaler or specialty distributor in compliance with the request.

"(D) IMMINENT HAZARD.—At any time, the Secretary may prohibit, limit, or otherwise suspend a transfer of a covered product to an eligible product developer if the Secretary determines that the transfer of such product to the eligible product developer would present an imminent hazard to the public health. In such cases, the Secretary shall specify the basis for the determination, including the specific information available to the Secretary which served as the basis for such determination, and confirm such determination in writing.

"(f) ENFORCEMENT.—

"(1) REMEDIES.—An eligible product developer that is aggrieved by a violation of subsection (b), (c), (d), (e)(1) or (e)(3) by a license holder may sue such license holder in a court of competent jurisdiction for injunctive relief and treble damages (including costs and interest of the kind described in section 4(a) of the Clayton Act (15 U.S.C. 15(a))).

"(2) RULE OF CONSTRUCTION.—

"(A) PRESERVATION OF ANTITRUST LAWS.—Nothing in this Act, or the amendments made by this Act, shall be construed to modify, supersede, or impair the operation of the antitrust laws.

"(B) DEFINITION.—For purposes of paragraph (1), the term 'antitrust laws' shall have the meaning given such term in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12), except that such term shall include section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such subsection applies to unfair methods of competition.

"(g) LIMITATION OF LIABILITY.—The holder of an approved application or license for a covered product shall not be liable for any claim arising out of an eligible product developer's failure to follow adequate safeguards to as-

sure safe use of the covered product during development or testing activities conducted under this section.".

(b) WAIVER OF SINGLE, SHARED SYSTEM REQUIREMENT.—Section 505–1(i)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(i)(1)(C)) is amended—

(1) in clause (i), by striking "or" at the end;

(2) in clause (ii), by striking the period at the end and inserting "; or"; and

(3) by inserting after clause (ii) the following:

"(iii) the applicant for an abbreviated new drug application certifies that it attempted in good faith to create or negotiate entry into a single, shared system, but was unable to finalize commercially reasonable terms with the holder of the listed drug within 120 days, and such certification includes a description of the efforts made by the applicant for the abbreviated new drug application to create or negotiate entry into a single, shared system.".

(c) EFFECTIVE DATE.—This section and the amendments made by this section shall take effect upon enactment, and shall apply to all approved applications or li-

censes for a covered product (as defined in section 505–2(a) of the Federal Food, Drug, and Cosmetic Act, as added by this section) regardless of whether those applications or licenses were approved before, on, or after the date of enactment of this Act.

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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. 1499

To prohibit brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

March 5, 2019

Mr. RUSH introduced the following bill; which was referred to the Committee on _____

A BILL

To prohibit brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market, and to prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Protecting Consumer Access to Generic Drugs Act of 2019".

SEC. 2. UNLAWFUL AGREEMENTS.

(a) AGREEMENTS PROHIBITED.—Subject to subsections (b) and (c), it shall be unlawful for an NDA or BLA holder and a subsequent filer to enter into, or carry out, an agreement resolving or settling a covered patent infringement claim on a final or interim basis if under such agreement—

(1) a subsequent filer directly or indirectly receives from such holder anything of value, including an exclusive license; and

(2) the subsequent filer agrees to limit or forego research on, or development, manufacturing, marketing, or sales, for any period of time, of the covered product that is the subject of the application described in subparagraph (A) or (B) of subsection (f)(8).

(b) EXCLUSION.—It shall not be unlawful under subsection (a) if a party to an agreement described in such subsection demonstrates by clear and convincing evidence that the value described in subsection (a)(1) is compensation solely for other goods or services that the subsequent filer has promised to provide.

(c) LIMITATION.—Nothing in this section shall prohibit an agreement resolving or settling a covered patent infringement claim in which the consideration granted by the NDA or BLA holder to the subsequent filer as part of the resolution or settlement includes only one or more of the following:

(1) The right to market the covered product that is the subject of the application described in subparagraph (A) or (B) of subsection (f)(8) in the United States before the expiration of—

(A) any patent that is the basis of the covered patent infringement claim; or

(B) any patent right or other statutory exclusivity that would prevent the marketing of such covered product.

(2) A payment for reasonable litigation expenses not to exceed $7,500,000 in the aggregate.

(3) A covenant not to sue on any claim that such covered product infringes a patent.

(d) ENFORCEMENT BY FEDERAL TRADE COMMISSION.—

(1) GENERAL APPLICATION.—The requirements of this section apply, according to their terms, to an NDA or BLA holder or subsequent filer that is—

(A) a person, partnership, or corporation over which the Commission has authority pursuant to section 5(a)(2) of the Federal Trade Commission Act (15 U.S.C. 45(a)(2)); or

(B) a person, partnership, or corporation over which the Commission would have authority pursuant to such section but for the fact that such person, partnership, or corporation is not organized to carry on business for its own profit or that of its members.

(2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES ENFORCEMENT AUTHORITY.—

(A) IN GENERAL.—A violation of this section shall be treated as an unfair or deceptive act or practice in violation of section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C. 45(a)(1)).

(B) POWERS OF COMMISSION.—Except as provided in subparagraph (C) and paragraphs (1)(B) and (3)—

(i) the Commission shall enforce this section in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade

Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section; and

(ii) any NDA or BLA holder or subsequent filer that violates this section shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act.

(C) JUDICIAL REVIEW.—In the case of a cease and desist order issued by the Commission under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of this section, a party to such order may obtain judicial review of such order as provided in such section 5, except that—

(i) such review may only be obtained in—

(I) the United States Court of Appeals for the District of Columbia Circuit;

(II) the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined in section 801.1(a)(3) of title 16, Code of Federal Regulations, or any suc-

cessor thereto, of the NDA or BLA holder is incorporated as of the date that the application described in subparagraph (A) or (B) of subsection (f)(8) is submitted to the Commissioner of Food and Drugs; or

(III) the United States Court of Appeals for the circuit in which the ultimate parent entity, as so defined, of the subsequent filer is incorporated as of the date that the application described in subparagraph (A) or (B) of subsection (f)(8) is submitted to the Commissioner of Food and Drugs; and

(ii) the petition for review shall be filed in the court not later than 30 days after such order is served on the party seeking review.

(3) ADDITIONAL ENFORCEMENT AUTHORITY.—

(A) CIVIL PENALTY.—The Commission may commence a civil action to recover a civil penalty in a district court of the United States against any NDA or BLA holder or subsequent filer that violates this section.

(B) SPECIAL RULE FOR RECOVERY OF PENALTY IF CEASE AND DESIST ORDER ISSUED.—

(i) IN GENERAL.—If the Commission has issued a cease and desist order in a proceeding under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of this section—

(I) the Commission may commence a civil action under subparagraph (A) to recover a civil penalty against any party to such order at any time before the expiration of the 1-year period beginning on the date on which such order becomes final under section 5(g) of such Act (15 U.S.C. 45(g)); and

(II) in such civil action, the findings of the Commission as to the material facts in such proceeding shall be conclusive, unless—

(aa) the terms of such order expressly provide that the Commission's findings shall not be conclusive; or

(bb) such order became final by reason of section 5(g)(1) of such Act (15 U.S.C. 45(g)(1)), in which case such findings shall be conclusive if supported by evidence.

(ii) RELATIONSHIP TO PENALTY FOR VIOLATION OF AN ORDER.—The penalty provided in clause (i) for violation of this section is separate from and in addition to any penalty that may be incurred for violation of an order of the Commission under section 5(l) of the Federal Trade Commission Act (15 U.S.C. 45(l)).

(C) AMOUNT OF PENALTY.—

(i) IN GENERAL.—The amount of a civil penalty imposed in a civil action under subparagraph (A) on a party to an agreement described in subsection (a) shall be sufficient to deter violations of this section, but in no event greater than—

(I) if such party is the NDA or BLA holder, the greater of—

(aa) 3 times the value received by such NDA or BLA

holder that is reasonably attributable to the violation of this section; or

(bb) 3 times the value given to the subsequent filer reasonably attributable to the violation of this section; and

(II) if such party is the subsequent filer, 3 times the value received by such subsequent filer that is reasonably attributable to the violation of this section.

(ii) FACTORS FOR CONSIDERATION.—In determining such amount, the court shall take into account—

(I) the nature, circumstances, extent, and gravity of the violation;

(II) with respect to the violator, the degree of culpability, any history of violations, the ability to pay, any effect on the ability to continue doing business, profits earned by the NDA or BLA holder, compensation received by the subsequent filer, and the amount of commerce affected; and

(III) other matters that justice requires.

(D) INJUNCTIONS AND OTHER EQUITABLE RELIEF.—In a civil action under subparagraph (A), the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law.

(5) PRESERVATION OF AUTHORITY OF COMMISSION.—Nothing in this section shall be construed to affect any authority of the Commission under any other provision of law.

(e) ANTITRUST LAWS.—Nothing in this section shall modify, impair, limit, or supersede the applicability of the antitrust laws as defined in subsection (a) of the first section of the Clayton Act (15 U.S.C. 12(a)), and of section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit, or supersede the right of a subsequent filer to assert claims or counterclaims against any person,

under the antitrust laws or other laws relating to unfair competition.

(f) DEFINITIONS.—In this section:

(1) AGREEMENT RESOLVING OR SETTLING A COVERED PATENT INFRINGEMENT CLAIM.—The term "agreement resolving or settling a covered patent infringement claim" means any agreement that—

(A) resolves or settles a covered patent infringement claim; or

(B) is contingent upon, provides for a contingent condition for, or is otherwise related to the resolution or settlement of a covered patent infringement claim.

(2) COMMISSION.—The term "Commission" means the Federal Trade Commission.

(3) COVERED PATENT INFRINGEMENT CLAIM.—The term "covered patent infringement claim" means an allegation made by the NDA or BLA holder to a subsequent filer, whether or not included in a complaint filed with a court of law, that—

(A) the submission of the application described in clause (i) or (ii) of paragraph (5)(A), or the manufacture, use, offering for sale, sale, or importation into the United States of a cov-

ered product that is the subject of such an application, infringes any patent owned by, or exclusively licensed to, the NDA or BLA holder of the covered product; or

(B) the covered product to be manufactured under such application uses a covered product as claimed in a published patent application.

(4) COVERED PRODUCT.—The term "covered product" means—

(A) a new drug (as defined in section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p))); or

(B) a biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))).

(5) NDA OR BLA HOLDER.—The term "NDA or BLA holder" means—

(A) the holder of—

(i) an approved new drug application filed under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) for a covered product; or

(ii) an application approved under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product;

(B) a person owning or controlling enforcement of the patent on—

(i) the list published under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) in connection with the application described in subparagraph (A)(i); or

(ii) the equivalent list published under section 351 of the Public Health Service Act (42 U.S.C. 262) comprised of patents associated with applications filed under section 351(a) of such Act (42 U.S.C. 262(a)); or

(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any entity described in subparagraph (A) or (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

(6) PATENT.—The term "patent" means a patent issued by the United States Patent and Trademark Office.

(7) STATUTORY EXCLUSIVITY.—The term "statutory exclusivity" means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 505(j)(5)(B)(iv) (180-day exclusivity), section 527 (orphan drug exclusivity), section 505A (pediatric exclusivity), or section 505E (qualified infectious disease product exclusivity) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 360cc, 355a, 355f), or section 351(k)(6) (interchangeable biological product exclusivity) or section 351(k)(7) (biological product reference product exclusivity) of the Public Health Service Act (42 U.S.C. 262(k)(6), (7)).

(8) SUBSEQUENT FILER.—The term "subsequent filer" means—

(A) in the case of a drug, a party that owns or controls an abbreviated new drug application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) or a new drug application filed under

section 505(b)(2) of such Act (21 U.S.C. 355(b)(2)) or has the exclusive rights to distribute the covered product that is the subject of such application; or

(B) in the case of a biological product, a party that owns or controls an application filed with the Food and Drug Administration under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) or has the exclusive rights to distribute the biological product that is the subject of such application.

(g) EFFECTIVE DATE.—This section shall apply to all agreements described in subsection (a) entered into after June 17, 2013, except that a civil penalty may only be obtained under subsection (d)(3)(A) with respect to such an agreement entered into on or after the date of enactment of this Act.

SEC. 3. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1111(7) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by inserting "or the owner of a patent for which a claim of infringement could reasonably be asserted against any person for making, using, offering to sell, selling, or importing into the United States a biological prod-

uct that is the subject of a biosimilar biological product application'' before the period at the end.

(b) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act (21 U.S.C. 355 note) is amended by adding at the end the following:

''(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement under subsection (a) or (b) that is required to be filed under subsection (c) shall, within 30 days of such filing, execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification—

'''(1) represent the complete, final, and exclusive agreement between the parties;

'''(2) include any ancillary agreements that are contingent upon, provide a contingent condition for, were entered into within 30 days of, or are otherwise related to, the referenced agreement; and

'''(3) include written descriptions of any oral agreements, representations, commitments, or prom-

ises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.".

SEC. 4. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting "section 2 of the Protecting Consumer Access to Generic Drugs Act of 2019 or" after "that the agreement has violated".

SEC. 5. COMMISSION LITIGATION AUTHORITY.

Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking "or" after the semicolon;

(2) in subparagraph (E), by inserting "or" after the semicolon; and

(3) by inserting after subparagraph (E) the following:

"(F) under section 2(d)(3)(A) of the Protecting Consumer Access to Generic Drugs Act of 2019;".

SEC. 6. STATUTE OF LIMITATIONS.

(a) IN GENERAL.—Except as provided in subsection (b), the Commission shall commence any administrative proceeding or civil action to enforce section 2 of this Act

not later than 6 years after the date on which the parties to the agreement file the Notice of Agreement as provided by section 1112(c)(2) and (d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

(b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND DESIST ORDER.—If the Commission has issued a cease and desist order under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) for violation of section 2 of this Act and the proceeding for the issuance of such order was commenced within the period required by subsection (a) of this section, such subsection does not prohibit the commencement, after such period, of a civil action under section 2(d)(3)(A) against a party to such order or a civil action under subsection (l) of such section 5 for violation of such order.

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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. 1503

To amend the Federal Food, Drug, and Cosmetic Act regarding the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

March 5, 2019

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act regarding the list under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Orange Book Transparency Act of 2019".

SEC. 2. ORANGE BOOK.

(a) PATENTS.—Clause (iii) of section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended to read as follows:

"(iii)(I) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

"(II) The Secretary—

"(aa) shall include on the list, from such patent information respecting a drug, drug substance (including active ingredient) patents, drug product (including formulation and composition) patents, and method of use patents; and

"(bb) may choose to include on the list additional patent information respecting the drug.

"(III) The Secretary shall not include on the list any patent to the extent such patent claims a device that is used for the delivery of the drug. Notwithstanding the preceding sentence, the Secretary may require (under other applicable provisions of law) the holder of the approved application for a drug to submit, for purposes other than the list under this paragraph, patent information respecting a device that is used for the delivery of the drug.".

(b) LISTING OF EXCLUSIVITIES.—Subparagraph (A) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

"(iv) For each drug included on the list, the Secretary shall specify each exclusivity period that is applicable and has not concluded under—

"(I) clause (iii) or (iv) of subsection (c)(3)(E) of this section;

"(II) clause (iv) or (v) of paragraph (5)(B) of this subsection;

"(III) clause (iii) or (iv) of paragraph (5)(F) of this subsection;

"(IV) section 505A;

"(V) section 505E; or

"(VI) section 527(a).".

(c) REMOVAL OF INVALID PATENTS.—

(1) IN GENERAL.—Section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)) is amended by adding at the end the following:

"(D)(i) The holder of an application approved under subsection (c) for a drug on the list shall promptly notify the Secretary in writing if either of the following occurs:

"(I) The Patent Trial and Appeals Board issues a decision that a patent for such drug is invalid.

"(II) A court issues a decision from which no appeal may be taken that a patent for such drug is invalid.

"(ii) The holder of an approved application shall include in any notification under clause (i) a copy of the decision described in subclause (I) or (II) of clause (i).

"(iii) The Secretary shall remove from the list any patent that is determined to be invalid in a decision described in subclause (I) or (II) of clause (i)—

"(I) promptly; but

"(II) not before the expiration of any 180-day exclusivity period under clause (iv) or (v) of paragraph (5)(B) that relies on a certification described in paragraph (2)(A)(vii)(IV) that such patent was invalid.".

(2) APPLICABILITY.—Subparagraph (D) of section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), as added by paragraph (1), applies only with respect to a decision described in such subparagraph that is issued on or after the date of enactment of this Act.

(d) REVIEW AND REPORT.—Not later than one year after the date of enactment of this Act, the Secretary of

Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) review the types of patent information that should be included on the list under section 507(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

(2) report to the Congress on the results of such review, including any recommendations about the types of patent information that should be included on or removed from such list.

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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. 1506

To amend the Federal Food, Drug, and Cosmetic Act to ensure that valid generic drugs may enter the market.

IN THE HOUSE OF REPRESENTATIVES

March 5, 2019

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure that valid generic drugs may enter the market.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Fair And Immediate Release of Generic Drugs Act" or the "FAIR Generics Act".

SEC. 2. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS REGARDING FIRST APPLICANT STATUS.

(a) AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) IN GENERAL.—Section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)) is amended—

(A) in clause (iv)(II)—

(i) by striking item (bb); and

(ii) by redesignating items (cc) and (dd) as items (bb) and (cc), respectively; and

(B) by adding at the end the following:

"(v) FIRST APPLICANT DEFINED.—As used in this subsection, the term 'first applicant' means an applicant—

"(I)(aa) that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug; and

"(bb) that has not entered into a disqualifying agreement described under clause (vii)(II); or

"(II)(aa) for the drug that is not described in subclause (I) and that, with respect to the applicant and drug, each requirement described in clause (vi) is satisfied; and

"(bb) that has not entered into a disqualifying agreement described under clause (vii)(II).

"(vi) REQUIREMENT.—The requirements described in this clause are the following:

"(I) The applicant described in clause (v)(II) submitted and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) or a statement described in paragraph (2)(A)(viii) for each unexpired patent for which a first applicant described in clause (v)(I) had submitted a certification described in paragraph (2)(A)(vii)(IV) on the first day on which a substantially complete application containing such a certification was submitted.

"(II) With regard to each such unexpired patent for which the applicant described in clause (v)(II) submitted a certification de-

scribed in paragraph (2)(A)(vii)(IV), no action for patent infringement was brought against such applicant within the 45-day period specified in paragraph (5)(B)(iii); or if an action was brought within such time period, such an action was withdrawn or dismissed by a court (including a district court) without a decision that the patent was valid and infringed; or if an action was brought within such time period and was not withdrawn or so dismissed, such applicant has obtained the decision of a court (including a district court) that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity, and including a settlement order or consent decree signed and entered by the court stating that the patent is invalid or not infringed).

"(III) If an applicant described in clause (v)(I) has begun commercial marketing of such drug, the applicant described in clause (v)(II) does not begin commercial marketing of such drug until the date that is 30 days after the date on which the applicant described in clause (v)(I) began such commercial marketing.".

(2) CONFORMING AMENDMENT.—Section 505(j)(5)(D)(i)(IV) of such Act (21 U.S.C. 355(j)(5)(D)(i)(IV)) is amended by striking "The first applicant" and inserting "The first applicant, as defined in subparagraph (B)(v)(I),".

(b) APPLICABILITY.—The amendments made by subsection (a) shall apply only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to which the amendments made by section 1102(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) apply.

SEC. 3. 180-DAY EXCLUSIVITY PERIOD AMENDMENTS REGARDING AGREEMENTS TO DEFER COMMERCIAL MARKETING.

(a) AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) LIMITATIONS ON AGREEMENTS TO DEFER COMMERCIAL MARKETING DATE.—Section 505(j)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)), as amended by section 2, is further amended by adding at the end the following:

"(vii) AGREEMENT BY FIRST APPLICANT TO DEFER COMMERCIAL MARKETING; LIMITATION ON

ACCELERATION OF DEFERRED COMMERCIAL MARKETING DATE.—

"(I) AGREEMENT TO DEFER APPROVAL OR COMMERCIAL MARKETING DATE.—An agreement described in this subclause is an agreement between a first applicant and the holder of the application for the listed drug or an owner of one or more of the patents as to which any applicant submitted a certification qualifying such applicant for the 180-day exclusivity period whereby that applicant agrees, directly or indirectly, (aa) not to seek an approval of its application that is made effective on the earliest possible date under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, (bb) not to begin the commercial marketing of its drug on the earliest possible date after receiving an approval of its application that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or (cc) to both items (aa) and (bb).

"(II) AGREEMENT THAT DISQUALIFIES APPLICANT FROM FIRST APPLICANT STATUS.—An agreement described in this subclause is an

agreement between an applicant and the holder of the application for the listed drug or an owner of one or more of the patents as to which any applicant submitted a certification qualifying such applicant for the 180-day exclusivity period whereby that applicant agrees, directly or indirectly, not to seek an approval of its application or not to begin the commercial marketing of its drug until a date that is after the expiration of the 180-day exclusivity period awarded to another applicant with respect to such drug (without regard to whether such 180-day exclusivity period is awarded before or after the date of the agreement).

"(viii) LIMITATION ON ACCELERATION.—If an agreement described in clause (vii)(I) includes more than 1 possible date when an applicant may seek an approval of its application or begin the commercial marketing of its drug—

"(I) the applicant may seek an approval of its application or begin such commercial marketing on the date that is the earlier of—

"(aa) the latest date set forth in the agreement on which that applicant can receive an approval that is made effective

under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or begin the commercial marketing of such drug, without regard to any other provision of such agreement pursuant to which the commercial marketing could begin on an earlier date; or

"(bb) 180 days after another first applicant begins commercial marketing of such drug; and

"(II) the latest date set forth in the agreement on which that applicant can receive an approval that is made effective under this subparagraph, subparagraph (F) of this paragraph, section 505A, or section 527, or begin the commercial marketing of such drug, without regard to any other provision of such agreement pursuant to which commercial marketing could begin on an earlier date, shall be the date used to determine whether an applicant is disqualified from first applicant status pursuant to clause (vii)(II).".

(2) NOTIFICATION OF FDA.—Section 505(j) of such Act (21 U.S.C. 355(j)) is amended by adding at the end the following:

"(11)(A) The holder of an abbreviated application under this subsection shall submit to the Secretary a notification that includes—

"(i)(I) the text of any agreement entered into by such holder described under paragraph (5)(B)(vii)(I); or

"(II) if such an agreement has not been reduced to text, a written detailed description of such agreement that is sufficient to disclose all the terms and conditions of the agreement; and

"(ii) the text, or a written detailed description in the event of an agreement that has not been reduced to text, of any other agreements that are contingent upon, provide a contingent condition for, or are otherwise related to an agreement described in clause (i).

"(B) The notification described under subparagraph (A) shall be submitted not later than 10 business days after execution of the agreement described in subparagraph (A)(i). Such notification is in addition to any notification required under section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

"(C) Any information or documentary material filed with the Secretary pursuant to this paragraph shall be ex-

empt from disclosure under section 552 of title 5, United States Code, and no such information or documentary material may be made public, except as may be relevant to any administrative or judicial action or proceeding. Nothing in this paragraph is intended to prevent disclosure to either body of the Congress or to any duly authorized committee or subcommittee of the Congress.".

(3) PROHIBITED ACTS.—Section 301(e) of such Act (21 U.S.C. 331(e)) is amended by striking "505 (i) or (k)" and inserting "505 (i), (j)(11), or (k)".

(b) INFRINGEMENT OF PATENT.—Section 271(e) of title 35, United States Code, is amended by adding at the end the following:

"(7) The exclusive remedy under this section for an infringement of a patent for which the Secretary of Health and Human Services has published information pursuant to subsection (b)(1) or (c)(2) of section 505 of the Federal Food, Drug, and Cosmetic Act shall be an action brought under this subsection within the 45-day period described in subsection (j)(5)(B)(iii) or (c)(3)(C) of section 505 of the Federal Food, Drug, and Cosmetic Act.".

(c) APPLICABILITY.—

(1) LIMITATIONS ON ACCELERATION OF DEFERRED COMMERCIAL MARKETING DATE.—The

amendment made by subsection (a)(1) shall apply only with respect to—

(A) an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to which the amendments made by section 1102(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) apply; and

(B) an agreement described under section 505(j)(5)(B)(vii)(I) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)(1)) executed after the date of enactment of this Act.

(2) NOTIFICATION OF FDA.—The amendments made by paragraphs (2) and (3) of subsection (a) shall apply only with respect to an agreement described under section 505(j)(5)(B)(vii)(I) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)(1)) executed after the date of enactment of this Act.

.....

(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. 1520

To amend the Public Health Service Act to provide for the publication of a list of licensed biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

March 5, 2019

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to provide for the publication of a list of licensed biological products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Purple Book Continuity Act of 2019".

SEC. 2. PUBLIC LISTING.

Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is amended by adding at the end the following:

"(9) PUBLIC LISTING.—

"(A) IN GENERAL.—

"(i) INITIAL PUBLICATION.—Not later than 60 days after the date of enactment of the Purple Book Continuity Act of 2019, the Secretary shall publish and make available to the public electronically—

"(I) a list in alphabetical order of the official and proprietary name of each biological product for which a biologics license under subsection (a) or this subsection is in effect as of such date of enactment;

"(II) the date of licensing if the biological product is licensed after 1981 and the number of the application which was approved; and

"(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will

refer to the biological product published.

"(ii) REVISIONS.—Every 30 days after the publication of the first list under clause (i), the Secretary shall revise the list to include each biological product which has been licensed under subsection (a) or this subsection during the 30-day period.

"(iii) PATENT INFORMATION.—When patent information has been provided by the reference product sponsor to the subsection (k) applicant respecting a biological product included on the list published under this subparagraph, the Secretary shall, in revisions made under clause (ii), include such information for such biological product.

"(B) DATE OF PUBLICATION.—A biological product for which a license is in effect under subsection (a) or this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the later of—

"(i) the date of its licensing; or

"(ii) the date of its publication in the list that—

"(I) was published under this section before the initial publication of the list under subparagraph (A); and

"(II) was equivalent to the list published under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act and comprised of patents associated with applications filed under subsection (a) of this section or under this subsection.

"(C) WITHDRAWAL OR SUSPENSION OF LICENSURE.—If the licensing of a biological product was withdrawn or suspended for safety, purity, or potency reasons, it may not be published in the list under subparagraph (A). If the withdrawal or suspension occurred after its publication in such list—

"(i) it shall be immediately removed from such list—

"(I) for the same period as the withdrawal or suspension; or

"(II) if the listed drug has been withdrawn from sale, for the period of

withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety, purity, or potency reasons; and

"(ii) a notice of the removal shall be published in the Federal Register.".

SEC. 3. REVIEW AND REPORT ON TYPES OF BIOLOGICAL PRODUCT PATENTS TO BE LISTED.

Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) complete a review of, and formulate recommendations on, the types of biological product patents that should be included in or removed from the list required by paragraph (9) of section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as added by section 2; and

(2) report such recommendations to the Congress.

March 2019 – FDA, CDER, Office of Generic Drug Policy

Measuring the cost of delayed ANDA approvals

This analysis considers the specific case of delays associated with situations described in the President's FY 2019 budget for HHS where a generic first applicant is not yet approved and the first applicant's 180-day exclusivity is blocking approval of subsequent generic applicants who would be approvable but for 180-day exclusivity.

Data

We used FDA records to identify occurrences of the scenario targeted by the 180-day exclusivity proposal in the President's FY 2019 budget from 2012 through 2017. We observed this scenario to occur approximately five times per year over this period.

We then identified the affected products in the IQVIA National Sales Perspective database, a data set that includes monthly dollar and unit sales of prescription drug products in the United States.[1] Eleven products for which this scenario occurred had adequate sales data both before and after generic entry allowing us to construct estimates of the potential cost savings associated with the proposal.[2]

Analysis – Limited to affected products

Combining the duration of the observed delay for each product with sales data from IQVIA, we estimate potential forgone cost savings that may have been realized if the delays in the first generic approval had not occurred. All dollar values used in this document are CPI-adjusted to a January 2018 base period:

Average delay per ANDA: 12 months, ranging from 2 to 24+ months
Average monthly forgone savings per drug due to delay: $29.5m
Average cost per delay: 12 months * $29.5m = $363m
Observed approximately 5 delays per year
Total forgone savings per year: 5 delays * $363m per delay = $1.8bn

These estimates are based on the observed dollar sales of the brand product during the delay, minus what these sales would have been if the units sold were held constant at their pre-generic level, but the average price of each product was instead set at the level observed after generic entry. Note that this average price accounts for the price and market share of both the brand and generic products after

[1] The IQVIA National Sales Perspectives™ measures the volume of prescription drug products moving from distributors and manufacturers into various outlets within the retail and non-retail markets. Volume is expressed in terms of sales dollars, eaches, extended units, and share of market. These data are estimated based on national projections. Outlets within the retail market include the following pharmacy settings: chain drug stores, independent drug stores, mass merchandisers, food stores, and mail service. Outlets within the non-retail market include clinics, non-federal hospitals, federal facilities, HMOs, long-term care facilities, home health care, and other miscellaneous settings.

[2] Among the products without adequate sales data, this included not having enough pre- or post-generic entry sales data available, recent delays with no generic sales yet available, or inconstancies in the sales data (e.g. no brand sales prior to generic sales, or generic sales listed well before the approval date of the first ANDA).

generic entry. The methods used to generate these estimates are more fully explained in the Technical Note below.

We note that although these estimates are consistent for the limited number of affected products in our 2012-2017 data set that also had sales data available, they may not be representative of cost savings derived from avoiding future delays. These estimates are sensitive to the observed market outcomes and these outcomes may vary in the future for different products, and complete sales data were available for only 11 products in our data set.

Among these 11 products the length of each delay also varied, ranging from 2 months to up to nearly 24 months. The total yearly pre-generic sales also varied; some of the 11 products were small-market drugs with pre-generic brand sales less than $100 million per year while some were large-market products with observed pre-generic brand sales well over $1 billion per year. The extent of the price reductions observed after generic entry also varied, ranging from about a 20% reduction up to nearly 90% price reductions in some cases.

Given the wide variations observed in the values used to estimate cost savings associated with averting delayed generic entry for these 11 products, and because FDA is aware these estimates may not be representative of future outcomes, we also examined (and present below) potential cost saving of this proposal based on an ongoing analysis conducted by FDA that measures the costs associated with delayed generic entry for a much broader group of products.

Analysis – Generalized cost savings

An obvious shortcoming of the above analysis is the limited number of products included. In the future we expect that a similar number of products will be affected by this policy proposal each year (5), but the length of each delay and the savings associated with each product will likely vary.

Using IQVIA sales data, we identified all products with an initial generic entry from the beginning of 2014 through the end of 2016. Observations for each product include brand-only sales for the 18 months before generic entry and sales with both brand and generic products on the market for the first 18 months after generic entry. In total we identified 80 products with initial generic entry and complete sales data during this period.

With both pre- and post-generic sales data available we can compute the costs of theoretical delays by answering this question: If these generic products were approved X months sooner and the observed monthly post-generic prices and market share were in place, how would the total spending at these prices compare to the observed spending when there were no generics on the market?

From this we estimate the following average costs of delays of the initial generic approval for theoretical delays lasting from 1 to 18 months. Estimates are per drug product:

Duration of theoretical generic delay (months)	Total savings estimate if the delay is avoided (millions)
1	$ 15.5
2	$ 34.0
3	$ 55.6
4	$ 76.5
5	$ 97.2
6	$ 121.4
7	$ 148.1
8	$ 173.8
9	$ 204.5
10	$ 235.8
11	$ 266.8
12	$ 299.8
13	$ 333.0
14	$ 366.1
15	$ 401.4
16	$ 435.7
17	$ 469.7
18	$ 504.2

If we use these cost of delay estimates with the number of products per year we identified as being delayed (5 products) and the average delay (12 months) we estimate the savings of avoiding these delays to be approximately $1.5bn per year ($299.8m per delay times 5 delays).

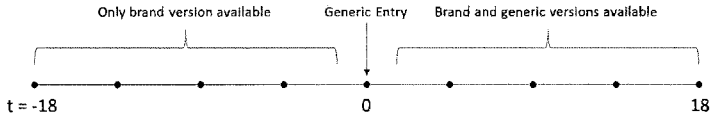
Considering that the length of delay varies from product to product we can see that the expected total costs of these delays will also vary. The above results help to better quantify the range of potential savings from averting delays. These results are based on 80 products that had recent initial generic entry and include a broad representation of product-specific variations in total annual brand sales (from less than $100m per year up to several billions of dollars per year) and also incorporate variations in price reductions associated with generic entry, both of which are directly deterministic of total cost savings associated with generic entry.

Technical note

This section explains the analysis used to estimate the generalized cost savings presented above.

During months t=-18, ..., -1 only the brand product is sold. Generic entry occurs in month t=0, and in months t=1, ..., 18 both the brand and generic versions are being sold. We drop the month of initial generic entry (t=0) as in most cases the generic is available for only part of that month. For example, a

generic that enters the market on the 24th on January is only sold for one week of that month, leading to the observed generic market share for that month to be much lower than the following months when generics are available for the entire month.



The average savings resulting from avoiding a theoretical delay of a duration of D months for the N observed products is equal to:

$$\frac{\sum_{i=1}^{N}\sum_{t=-D}^{-1} DollarSales_{i,t} - [UnitSales_{i,t} * (Share_{t+D+1}^{Brand} * Price_{t+D+1}^{Brand} + Share_{t+D+1}^{Generic} * Price_{t+D+1}^{Generic})]}{N}$$

In words, this estimate is equal to the observed dollar sales in the pre-generic months ($DollarSales_{i,t}$) minus what the dollar sales would have been in these months if the total units sold were the same ($UnitSales_{i,t}$) but the market share of brand and generic products and the price of brand and generic products were instead in place once generics entered the market. For example, for a theoretical delay of 18 months (D=18) sums the savings from based on monthly sales summed over the 18 months prior to generic entry if the prices were at their corresponding post-generic levels. This is equal to the total estimated savings in month -18 (i.e. 18 months prior to generic entry) minus what these sales would have been if the prices and market share were what was observed in the first month of generic entry (t=1 = t+D+1 = -18+18+1), plus the sales from month -17 using the month 2 shares and prices, ..., plus the sales from month -1 using the month 18 shares and prices. The final estimate is the per product average savings associated with averting a delay of a specified duration (from 1 to 18 months) based on the 80 products in the sample.

We estimate the average per product cost of delay separately for each theoretical duration of a delay, with a separate savings estimate for each delay from 1 through 18 months. This is important to note as we expect longer delays to yield a per-month cost that is disproportionately higher than shorter delays. For example, the savings associated with avoiding a one-month delay are derived from price reductions associated only with the products that enter during this month (i.e. only savings from month t=-1). In contrast, a delay of 18 months will derive savings of the approvals that would have occurred in the first month, plus all other approvals occurring over the following 18 months (i.e. the sum of savings from month t=-1 through t=-18). Drug prices continue to drop as more generic versions are approved, so over time the market entry of additional generic products will lead to additional savings.

AdvocateAuroraHealth

March 13, 2019

Chairwoman Anna G. Eshoo
Health Subcommittee
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Ranking Member Michael Burgess, MD
Health Subcommittee
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Re: Written Testimony for the Hearing Record Submitted to the Health Subcommittee of the Committee on Energy & Commerce of the U.S. House of Representatives "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition."

Dear Chairwoman Eshoo and Ranking Member Burgess:

On behalf of Advocate Aurora Health (Advocate Aurora), I would like to commend you for holding a hearing on March 13, 2019 to discuss "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition." We maintain a strong commitment to innovation in health care delivery and stand ready to work with you and your colleagues to promote policy solutions and leverage innovation to reduce health care costs and improve affordability, access, and outcomes. Thank you for your leadership on this important topic and for the opportunity to submit this letter for the hearing record.

Background

Last year, Illinois-based Advocate Health Care (Advocate) and Wisconsin-based Aurora Health Care (Aurora) combined to become Advocate Aurora, the 10th largest not-for-profit integrated health care system in the country. Advocate Aurora is a national leader in clinical innovation, health outcomes, consumer experience, and value-based care. Together, each year, across more than 500 sites of care in Illinois and Wisconsin, we serve more than 2.7 million patients, including an estimated 500,000 Medicare beneficiaries and more than 450,000 individuals with Medicaid coverage.

Both legacy organizations have been transformative leaders and strong partners with the federal government, state governments, and commercial payors in the journey to value. With more than one million value-based lives, Advocate has one of the largest Accountable Care Organizations (ACOs) in the country and is a convener in the new Bundled Payment for Care Improvement-Advanced (BPCI-A) program. Aurora also was an early adopter of value-based programs, a successful Comprehensive Care for Joint Replacement (CJR) participant, a successful Medicare Shared Savings Program (MSSP) participant, and now manages a commercial ACO product in which we exchange clinical data, co-manage patient cases, and enhance patient health outcomes.

Value-Based Care for Drug Purchasing

Advocate Aurora is helping to lead the country in the transition to value-based care, transforming our health system from a volume-based approach towards one that rewards better outcomes at a lower cost. While significant strides have been made in developing and implementing value-based payment models for hospitals and physicians, little work has been done to create and test value-based drug

purchasing models or to include prescription drugs in the value equation. We respectfully request the Committee's consideration of proposals that would help to advance the design and implementation of such arrangements for drugs, such as:

- ***Indications-based pricing.*** This model would vary the payment for a drug based on its clinical effectiveness for the different indications for which it has been approved. Manufacturers would be paid more when treatments are used for indications for which they have higher value ("high-value indications") and less for indications for which they confer less benefit ("low-value indications"). This indication-specific pricing is designed to give patients more options.

- ***Risk-sharing agreements based on outcomes.*** This model would link the price of a drug with patient health outcome goals. Under an outcome-based agreement the final price of a drug would be tied to results achieved by specific patients. Manufacturers would agree to provide rebates, refunds, or price adjustments if the product does not meet targeted outcomes.[1]

Advocate Aurora Joins Other Leading Systems to Combat High Drug Prices and Shortages

In January of 2019 Advocate Aurora became a founding member of Civica Rx, a not-for-profit generic drug company established by a large group of integrated health systems representing more than 750 hospitals intent on battling shortages of generic drugs and bringing down the cost of those medications by manufacturing their own.

For instance, we have experienced increases between 15% to 20% over the past two years for the unit prices of immunosuppressants, which are drugs used to treat rheumatoid arthritis and other auto-immune conditions. Our system also faces intermittent shortages of sodium-bicarbonate, the sterile form of baking soda which is used during advanced cardiac life support and as an antidote to some poisons. The shortage carries serious consequences including possible delayed heart surgeries and caring for other emergency events when a patient's blood is too acidic, which can be fatal without proper treatment. In addition, our system was severely impacted in 2017 by a shortage of sodium chloride which is used to rehydrate patients and to dilute medications from antibiotics to painkillers to cancer drugs. We were forced to find alternative supplies, change the way we administered these drugs and to devise backup plans to make the fluids internally.

Our membership in Civica Rx will help us to supply our patients with a more reliable source of generic drugs, at affordable prices. Initially, Civica Rx expects to support the supply chains of its members by bringing more than 14 hospital-administered generic drugs such as sterile injectables into development this year. Civica Rx is working towards the goal of becoming an FDA-approved manufacturer and will either directly manufacture generic drugs or sub-contract manufacturing to trusted supply partners. Following the initial tranche of 14 therapies, the organization has plans to prioritize the development of additional medications that are in great demand but have limited availability.

[1] For more background please see, Value-based pricing vs. outcomes-based contracting. https://drugpricinglab.org/our-work/value-based-pricing-vs-outcomes-based-contracting/

AdvocateAuroraHealth

Support the CREATES Act

Advocate Aurora thanks the Subcommittee for its consideration of numerous policy proposals aimed at increasing the availability and affordability of generic medications. In particular, we support H.R. 965, the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (CREATES Act), and respectfully request all members of the Committee to support and advance this important, bipartisan legislation through Committee.

The CREATES Act will help promote drug price competition by making it easier for medicines whose patents have expired to be sold as less expensive generic versions. Currently drug companies are permitted to engage in anticompetitive behavior to block and delay entry of generic drugs. The bill would create a speedier and stronger legal process for generic manufacturers to challenge branded drug manufacturers that are withholding drug samples to obstruct generic competition. In addition, we are pleased that lawmakers also are considering other measures to spur greater generic competition in the marketplace including the BLOCKING Act; the FAIR Generics Act; the Purple Book Continuity Act; the Orange Book Transparency Act; and the FAST Generics Act.

Conclusion

In conclusion, Advocate Aurora appreciates the opportunity to submit this letter for the hearing record and stands ready to partner with you and your colleagues to increase the availability of affordable prescription therapies, including a more robust generics market. Advocate Aurora stands ready to work with you and your Committee colleagues to advance policy proposals that will reduce prescription drug costs for patients and providers, strengthen the generic marketplace and available supply of much-needed therapies, and help reduce the pressure that the high cost of drugs has placed on our federal budget and economy. If we can be of any assistance on this or other health policy matters, please do not hesitate to contact me or Meghan Woltman, Advocate Aurora, Vice President, Government and Community Relations, (630/929-6614, Meghan.Woltman@AdvocateHealth.com). Thank you for your consideration.

Sincerely,

Tom Woller, RPh, MS, FASHP
System Vice President, Pharmacy Services
Advocate Aurora Health

AARP®
Real Possibilities

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February 5, 2019

The Honorable David Cicilline
U.S. House of Representatives
2233 Rayburn House Office Building
Washington, DC 20515

The Honorable Jim Sensenbrenner
U.S. House of Representatives
2449 Rayburn House Office Building
Washington, DC 20515

The Honorable Peter Welch
U.S. House of Representatives
2187 Rayburn House Office Building
Washington, DC 20515

The Honorable David B. McKinley
U.S. House of Representatives
2239 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Cicilline, Sensenbrenner, Welch and McKinley:

AARP is pleased to endorse the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act that would deter brand name pharmaceutical companies from participating in certain practices that can delay or block the availability of less expensive generic and biosimilar drugs. We appreciate your bipartisan leadership in introducing this legislation to help make lower cost prescription drugs more available to seniors.

Rising prescription drug costs have been devastating to many Americans, especially those aged 50 and over who depend on prescription drugs to keep them healthy. The growing number of brand name and specialty drugs with remarkably high prices -- $100,000 or more -- has led many to question whether the costs associated with these products are defensible or sustainable. The timely availability of generic and biosimilar drugs – by increasing competition and helping to lower prices --will play an important role in addressing these concerns.

The Food and Drug Administration (FDA)-required Risk Evaluation and Mitigation Strategies (REMS) were originally designed to ensure that the benefits of a drug or biologic outweigh its risks. Unfortunately, brand name drug manufacturers are increasingly using REMS programs to effectively block generic drug and biosimilar product development. Left unchecked, these unnecessary delays could cost consumers, government programs, taxpayers, and the health care system billions of dollars annually.

The CREATES Act appropriately targets two forms of anticompetitive behavior that brand name drug manufacturers can use to stifle generic and biosimilar drug entry: refusal to provide access to product samples that are needed to gain FDA approval, and preventing generic and biosimilar manufacturers from joining a distribution protocol applicable to both brand and generic versions of a medicine, or "shared REMS." Additionally, courts would be empowered to award damages that would provide sufficient incentives to encourage good-faith dealing by brand manufacturers from the outset.

Importantly, the CREATES Act does not undermine or alter any of FDA's existing safety protocols pertaining to drug approval or distribution. In fact, this legislation requires the FDA to review and approve a generic manufacturer's application for a covered product subject to a REMS to ensure the manufacturer will adhere to the appropriate safety protections. Moreover, FDA is empowered to impose additional safety protocols on the generic manufacturer if they determine such measures are needed.

We look forward to working with you and your colleagues on both sides of the aisle in support of advancing the CREATES Act. If you have any further questions, please feel free to contact me, or have your staff contact Amy Kelbick at (202) 434-2648 on our Government Affairs staff.

Sincerely,

Joyce A. Rogers

Joyce A. Rogers
Senior Vice President
Government Affairs

AFSCME
We Make America Happen

March 12, 2019

The Honorable Anna G. Eshoo
Chairwoman, Subcommittee on Health
Committee on Energy and Commerce
U. S. House of Representatives
Washington, D.C. 20515

The Honorable Michael C. Burgess
Ranking Member, Subcommittee on Health
Committee on Energy and Commerce
U. S. House of Representatives
Washington, D.C. 20515

Dear Chairwoman Eshoo and Ranking Member Burgess:

On behalf of the members of the American Federation of State County and Municipal Employees (AFSCME), I am writing in support of the subcommittee's efforts to examine legislative proposals to lower prescription drug prices for all Americans. It shouldn't matter whether people get their health coverage through employer-sponsored insurance, Medicare, Medicaid or other sources; drug prices are too high and drug companies have gone unchecked for too long.

In fact, when there is no limit on prescription drug prices, we all suffer. Families have a tougher time getting access to lifesaving medications and treatments. The high cost of drugs is passed onto working families through higher premiums and increased cost-sharing. The struggle to pay for costly medicines puts the financial security of families in jeopardy. Even with health care insurance, out-of-pocket costs for prescription drugs can take a financial toll. For example, adult cancer patients are 2.65 times more likely to file for bankruptcy than their cohorts without cancer.

We want to highlight three bills being considered today that deserve support. These proposals tackle ways in which drug companies seek to erect barriers to the availability of more affordable prescription drugs.

The "CREATES Act of 2019" (H.R. 965) would help put a stop to games played by brand name drug companies to impede competition from generics. Some brand name drug companies delay or deny the sales of samples needed to conduct testing necessary for purposes of FDA approval. Some brand name companies also obstruct the development of needed shared safety procedures for both brand name and generic versions of a drug. These efforts thwart the development and market entry of generics. H.R. 965 would give key stakeholders the needed authority and tools to stop these dilatory practices and allow safe generics to be developed and accessible.

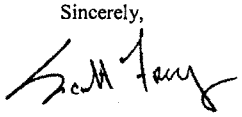
American Federation of State, County and Municipal Employees, AFL-CIO
TEL (202) 429-1000 FAX (202) 429-1293 TDD (202) 659-0446 WEB www.afscme.org 1625 L Street, NW, Washington, DC 20036-5687

The "FAST Generics Act of 2019" (H.R. 985) also seeks to address the delay tactics brand name drug companies use to deny adequate quantities of samples for testing needed to develop generic versions. It also addresses efforts to block the development of a single shared safety procedure.

The "Protecting Consumers Access to Generic Drugs Act" (H.R. 1499) would make it illegal for brand name and generic drug companies to enter into "pay-for-delay" agreements. Brand name drug companies use these anticompetitive agreements to keep generic equivalents off the market as their patent exclusivity is ending.

We encourage the subcommittee to move forward on these and other legislative proposals to lower drug prices.

Sincerely,



Scott Frey
Director of Federal Government Affairs

SF:LB:rf

Subcommittee on Health
House Committee on Energy and Commerce

Hearing on: "Lowering the Cost of Prescription Drugs:
Reducing Barriers to Market Competition"

March 13, 2019

Statement for the Record
Submitted by ASHP

American Society of Health-System Pharmacists
4500 East West Highway, Suite 900
Bethesda, MD 20814
Email: gad@ashp.org
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ASHP Statement for the Record
Subcommittee on Health, House Committee on Energy and Commerce: "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"
March 13, 2019

ASHP (American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the Subcommittee on Health, House Committee on Energy and Commerce hearing on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition."

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 50,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP's vision is that medication use will be optimal, safe, and effective for all people all of the time. A primary tenet of that vision includes access to affordable medications needed to save or sustain lives. Addressing the issue of skyrocketing drug prices, including excessive price increases on commonly used generic medications, is one of ASHP's highest and longstanding public policy priorities. According to a Kaiser Health Tracking Poll, 1 in 4 Americans cannot afford their medications.[1] Poor access to medications can lead to increased morbidity and mortality, and can cause healthcare costs to increase.

ASHP has been proactively addressing challenges related to the rapid increase of prescription drug pricing on several fronts, including working with like-minded stakeholders and educating members of Congress about the unsustainable burdens faced by patients, healthcare providers, and the entire healthcare system.

ASHP is a lead member of the Steering Committee of the Campaign for Sustainable Rx Pricing (CSRxP), a coalition of prominent national organizations representing physicians, consumers, payers, hospitals, health systems, and patient advocacy groups. CSRxP has developed a policy platform promoting market-based solutions supported by three pillars: competition, value, and transparency.

The goal of the campaign is to identify policy options that have bipartisan support and, therefore, a greater likelihood of passage. To that end, CSRxP focuses on policies to incentivize a more competitive marketplace to help stimulate lower drug prices. The campaign has also expressed support for efforts to loosen restrictions that prevent generic drug companies from obtaining the samples necessary to manufacture a competing product.

ASHP, along with the American Hospital Association (AHA) and the Federation of American Hospitals (FAH), recently released a report on the impact that the cost of and access to prescription drugs are having on hospital budgets and operations.

Specifically, the report showed that:

- Average total drug spending per hospital admission increased by 18.5% between fiscal year (FY) 2015 and FY2017.
- Outpatient drug spending per admission increased by 28.7%, while inpatient drug spending per admission increased by 9.6% between FY2015 and FY2017.

[1] DiJulio, Bianca, et al. "Kaiser Health Tracking Poll: August 2015." The Henry J. Kaiser Family Foundation, The Henry J. Kaiser Family Foundation, 20 Aug. 2015, https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/. Accessed February 10, 2019.

- Hospitals experienced price increases of over 80% across different classes of drugs, including those for anesthetics, parenteral solutions, and chemotherapy.
- Over 90% of surveyed hospitals reported having to identify alternative therapies to manage spending.
- One in 4 hospitals had to cut staff to mitigate budget pressures.

ASHP does not collect, store, or report drug pricing information. However, we continually hear from pharmacy leaders in hospitals and health systems that sudden, inexplicable, and unpredictable price increases in connection with some of the most commonly used, longstanding generic medications are becoming more prevalent — and are occurring on a nationwide basis.

We appreciate the committee's consideration of legislation designed to increase competition. Improving generics competition could not only reduce out-of-pocket costs, but also significantly strengthen the medication supply chain. Specifically, in 2018, clinicians faced acute shortages of the most basic generic products necessary for almost all patient care, including sterile water, sodium bicarbonate, small-volume parenterals, and injectable opioids. Such shortages jeopardize patient safety and siphon clinician resources away from direct patient care to shortage management, resulting in significant systemic costs, including increased prices. As we have worked diligently to address the issue of drug shortages for nearly 15 years, we urge the committee to explore means to incentivize generic competition and manufacturing upgrades to reduce and eventually eliminate shortages.

Although drug shortages are caused by a number of factors, when drugs in short supply are produced by only one or two manufacturers, prices increase. Stimulating market presence could help temper these price spikes. Thus, ASHP urges the committee to look at ways to incentivize marketplace participation. ASHP supports two bills being considered today: H.R. 985, the Fair Access for Safe and Timely (FAST) Generics Act of 2019" and H.R. 1499, the "Protecting Consumer Access to Generic Drugs Act of 2019." We believe that both bills would potentially increase competition. H.R. 985 would amend the Federal Food, Drug, and Cosmetic Act to ensure that eligible generic and biosimilar developers have competitive access to reference products, which is necessary in the development of generic drugs and biosimilars. H.R. 1499 would prohibit companies from engaging in "pay-to-delay" tactics, which stifle generic and biosimilar entry into the market.

Finally, we note that, in some cases, Risk Evaluation and Mitigations Strategies (REMS) have been used to circumvent generics competition. ASHP recognizes that manufacturer-driven REMS are necessary to ensure the safe use of certain medications. However, REMS programs should never be used to artificially inflate drug prices, nor should they interfere with the professional practice of pharmacists, physicians, nurses, and other providers. We believe there are cases in which manufacturer-driven REMS programs that require restricted distribution directly impact pricing, thereby increasing costs, reducing patient access, and delaying treatment. There is also evidence to suggest that the use of restricted or limited distribution channels has resulted in the inability of a potential competitor to acquire enough of a drug to conduct the required testing to bring a generic competitor to market. For this reason, we support H.R. 965, the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019." This bipartisan bill will help ensure that brand-name pharmaceutical companies cannot manipulate regulatory rules to prevent competition, which is essential for patient access to affordable medications. Additionally, we recommend that Congress require the Food and Drug Administration (FDA) to

investigate the use of restricted distribution REMS as a means to artificially increase drug prices and limit access to critical medications. Restricting distribution of medications is often a means to push patients to a specific purchasing channel, which in some cases increases not only their out-of-pocket costs, but also systemic costs. Further, restricted distribution networks can complicate patient access to critical medications, potentially disrupting care.

CONCLUSION

ASHP thanks the Subcommittee on Health, House Committee on Energy and Commerce for holding this important hearing. ASHP remains committed to working with Congress and industry stakeholders to ensure that patients have affordable access to lifesaving and life-sustaining medications.

March 12, 2019

The Honorable Frank Pallone, Jr.
Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
House Committee on Energy & Commerce
2322 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone and Ranking Member Walden:

On behalf of the millions of patients and consumers we collectively represent, we write today in support of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 (H.R. 965/ S. 340). The CREATES Act takes important steps to stop the now well-established abuse of one of the Food and Drug Administration's (FDA) primary safety programs that prevents lower-cost generics from being developed. Public health is undermined when pharmaceutical companies circumvent the FDA's rules with the sole purpose of delaying competition. We urge the Committee to advance this critical patient-focused legislation to enhance competition and maintain the FDA's role in ensuring the highest level of patient safety.

Over ten years ago, Congress provided the FDA with a new tool to further assure the safe use of prescription drugs. The Food and Drug Administration Amendments Act of 2007 allowed for Risk Evaluation and Mitigation Strategy (REMS) programs to be put in place to ensure the safe handling and distribution of certain drugs. In response to concerns that the new requirements would provide a new avenue for anti-competitive behavior, Congress specified that this new tool should not be gamed in a way to delay patient access to more affordable generic medicine.

Abuse of the FDA's safety programs, unfortunately, occurred in spite of congressional intent and has only increased over time. The FDA now reports more than 170 complaints across 55 different medicines have been received by the agency as of February 2019.

Pam Holt is a retired teacher from Indiana who suffers from multiple myeloma. To keep her cancer at bay, she takes the drug Revlimid with a list price of over $250,000 per year. Even on Medicare Part D the drug was unaffordable, and after just one year it sent Pam $10,000 into debt. She made the heartbreaking decision to refinance her house to afford the drug.

Revlimid is just one example of abuse of our current system. Its manufacturer, Celgene, has refused to provide product samples to generic competitors looking to create a lower-cost alternative. The CREATES Act will address these abuses and encourage generic drug competition. It achieves this while protecting patient safety.

The CREATES Act codifies the FDA's current practice of ensuring generic drug manufacturers are able to safely handle branded doses and that all materials contain comparable safety protections. All bioequivalence testing is subject to review by an institutional review board and must comply with patient informed consent provisions. These elements importantly provide another layer of protection for patients.

Moreover, the FDA must assure the same level of patient safety is provided when determining whether to waive the shared safety protocols. Notably, the CREATES Act maintains the requirement in current law that a different system will provide comparable protections for patients. As FDA leadership has noted, a single shared system will continue to be the agency's goal and only waived when the public health impact of delayed generic entry outweighs the benefits of a shared system.

Our organizations strongly believe in the FDA's ability to ensure patient safety when it comes to the process of obtaining samples and providing limited waivers to the shared safety protocols. The CREATES Act enhances and maintains the FDA's patient safety role, while ending the abuse of its safety programs. We encourage all members of the committee to support the CREATES Act as introduced.

Thank you for considering our views.

Sincerely,

AARP
Friends of Cancer Research
National Multiple Sclerosis Society
Patients for Affordable Drugs

the campaign for
SUSTAINABLE Rx PRICING
Transparency. Competition. Value.

February 15, 2019

The Honorable David Cicilline
United States House of Representatives
Washington, DC 20515

The Honorable Jim Sensenbrenner
United States House of Representatives
Washington, DC 20515

The Honorable Peter Welch
United States House of Representatives
Washington, DC 20515

The Honorable David McKinley
United States House of Representatives
Washington, DC 20515

Dear Representatives Cicilline, Sensenbrenner, Welch, and McKinley:

We, the undersigned, commend you for your leadership, commitment to reducing out-of-control prescription drug prices, and efforts to stop anti-competitive abuses that keep drug prices high for patients. On the reintroduction of this legislation in the 116th session of Congress, we again pledge our support for the CREATES Act and look forward to working with you to get this bill across the finish line this year.

The CREATES Act is a bipartisan, market-based solution to increase competition and thus lower prescription drug prices for patients and consumers. This reform helps speed the introduction of generic and biosimilar medicines by facilitating the purchase of brand name drug samples on market-based terms from pharmaceutical companies who otherwise would use anticompetitive tactics to block access. The CREATES Act will help ensure that brand-name pharmaceutical companies cannot take advantage of regulatory rules to forestall the competition that is essential for access and innovation. With its enactment, the CREATES Act will save patients and taxpayers $3.9 billion over ten years, according to the Congressional Budget Office, by allowing lower-priced generic drugs to enter the market earlier.

We also recognize and appreciate the commitment from Health and Human Services (HHS) Secretary Alex Azar and Food and Drug Administration Commissioner (FDA) Scott Gottlieb, M.D. on this important issue. Both have elevated awareness of brand manufacturer "gaming" of FDA regulatory rules to deny would-be generic competitors the ability to purchase samples of brand-name drugs necessary to conduct the FDA-required testing and bring more affordable medicines to market. Secretary Azar recently noted: "We know that certain brand-name manufacturers are abusing the system by blocking access to samples and hiding behind FDA's rules when they do it...They're using laws intended to promote the public health to pad their profits instead." Moreover, last year, the FDA released new guidance and published a database identifying more than 160 instances where access to samples was at issue.

Unfortunately, the use of these anti-competitive tactics has increased over the years and the cost to patients, health care providers, and taxpayers now amounts to billions of dollars annually. The CREATES Act would deliver those savings to patients by establishing a clear process for FDA to ensure the appropriate safety measures are in place, as well as a limited legal pathway that can be used only in

instances when a brand company has continued unjustifiably to deny the purchase of samples. In testimony before Congress, the Federal Trade Commission offered its support of the CREATES Act as it "protects the competitive process by eliminating incentives and opportunities for branded manufacturers to engage in manipulation of the REMS process to delay generic entry."

Thank you again for introducing the CREATES Act and for your leadership in advancing meaningful solutions to lower the prices of prescription drugs. We look forward to working with you to advance this bipartisan solution into law this year.

Sincerely,

AARP
Academy of Managed Care Pharmacy
AFL-CIO
Alliance of Community Health Plans
Alliance for Retired Americans
American Academy of Dermatology Association
American Academy of Family Physicians
American College of Physicians
American Consumer Institute
American Gastroenterological Association
America's Health Insurance Plans
American Hospital Association
Anthem
ASHP
Association for Accessible Medicines
Blue Cross Blue Shield Association
Blue Cross Blue Shield of Michigan
Blue Shield of California
Campaign for Sustainable Rx Pricing
Center for Freedom and Prosperity
Coalition to Reduce Spending
Consumer Action
Consumer Reports
CVS Health
Doctors for America
Families USA
Federation of American Hospitals
FreedomWorks
Friends of Cancer Research
Frontiers of Freedom
Healthcare Supply Chain Association
Innovation Defense Fund
Institute for Liberty
Kaiser Permanente
Knowledge Ecology International
National Coalition on Health Care
National Multiple Sclerosis Society
Patients for Affordable Drugs
Pharmaceutical Care Management Association
Premier healthcare alliance
Public Citizen

March 13, 2019

The Honorable Anna Eshoo
Chairperson
House Committee on Energy and Commerce
Subcommittee on Health
Washington, DC 20515

The Honorable Michael Burgess, MD
Ranking Member
House Committee on Energy and Commerce
Subcommittee on Health
Washington, DC 20515

Dear Chairperson Eshoo and Ranking Member Burgess:

On behalf of the American Academy of Family Physicians (AAFP), which represents 131,400 family physicians and medical students across the country, I write to share the organization's recommendations for how to manage drug prices and reduce out-of-pocket costs for consumers. The AAFP is also pleased to share its support for several bills under the committee's review.

Managing prescription drug prices for their patients is an important concern for family physicians. Family physicians have a meaningful interest in the drug pricing debate, in part, because of the complexity of care they provide and the fact that the number and intricacy of conditions, complaints, and diseases seen in family medicine is far greater than those seen by any other physician specialty. Ensuring access to medications is an integral part of a physician's role as an advocate for their patients. Unfortunately, and too frequently, family physicians encounter patients who cannot afford their medications and thus cannot adhere to treatment recommendations. Physicians themselves also face recurrent and burdensome administrative requirements like prior authorizations that create treatment barriers. According to a 2017 American Medical Association survey, 92 percent of physician respondents reported care delays due to prior authorizations and 78 percent reported that prior authorizations can lead to treatment abandonment.

The AAFP has long supported policies to ensure the availability of effective, safe, and affordable prescription medications. In 2017, the AAFP became a member of the Campaign for Sustainable Rx Pricing (CSRxP), a nonpartisan coalition of nonprofit medical associations, insurers, and hospitals committed to addressing drug price increases by striking a balance between drug innovation and affordability.

Given the public's reliance on generic products, which represent over 89 percent of medications filled, increasing access to these products must be a top priority. Although the Food and Drug Administration has accelerated the generic drug approval process, barriers remain for manufacturing new generic products, resulting in price escalation. An April 2015 Medscape article cited many factors that cause escalating costs, including strategies that delay or discourage competition by generic drug manufacturers.

Therefore, the AAFP is pleased to support the following bills that would increase access to generic drugs through enhanced market competition:

- HR 965, *Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act*;
- HR 985, the *Fair Access for Safety and Timely (FAST) Generics Act*;
- HR 938, the *Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019*; and
- HR 1499, the *Protecting Consumer Access to Generic Drugs Act of 2019*.

In a 2018 letter to the Department of Health and Human Services, the AAFP highlighted our principles and urged the administration to use its administrative authority to weigh in on legislative proposals that may also strengthen the nation's ability to control drug costs and out-of-pocket spending for patients. The following are select priorities for addressing the nation's drug pricing.

Site Neutral Payments.
Under Medicare Part B and often in Medicaid, physicians are reimbursed comparable amounts for drugs they administer to patients, but the facility fees when drugs are administered at hospitals and hospital-owned outpatient departments are many times higher than the fees charged by physician offices. **The AAFP supports site neutral payment policies for physician-administered drugs and urges Congress to consider further expansion of site neutral payments for outpatient services.** Researchers found that payments for physician visits at a hospital were $68 higher on average than for those at stand-alone offices. The authors also reviewed changes in price associated with physicians integrated with hospital systems. In the markets studied, annual outpatient spending increased by $75 per Medicare patient, "almost entirely owing to price increases rather than changes in utilization."

A report by the Government Accountability Office (GAO) showed between 2007 and 2013, the number of hospitals that achieved vertical integration with physician practices increased from 1,400 to 1,700, while the number of physicians with a hospital affiliation increased from 96,000 to 182,000. The report indicated Medicare paid $51 more for midlevel evaluation and management visits performed in a hospital outpatient setting compared to those at independent physician practices. The agency noted, "the inconsistency in Medicare payment policy is not justified. While vertical consolidation has potential benefits, we found that the rise in vertical consolidation exacerbates a financial vulnerability in Medicare's payment policy: Medicare pays different rates for the same service, depending on where the service is performed," the GAO report stated.

Value-Based Drug Pricing
In March of 2016, CMS proposed a value-based drug pricing demonstration project that establishes a common reimbursement for Medicare Part B drugs, implements purchasing agreements with drug manufacturers based on drug effectiveness, and includes clinical decision support tools. The transformation of our health care system requires fresh perspectives and new ideas regarding payment and delivery of health care services. The AAFP applauded CMS' efforts to apply common sense, value-based payment (VBP) principles to the delivery of physician-administered pharmaceutical and biologic treatments. VBP involves linking payment for drugs to patient outcomes and cost-effectiveness rather than volume of sales. **Physicians, hospitals, and other Medicare providers are**

aggressively pursuing VBP models, and HHS should explore the applicability of VBP principles and models to the pharmaceutical industry.

Medicare Negotiation Authority
According to a 2016 article, from 2004 to 2014, Medicare's share of U.S. drug expenditures increased from 2 percent of total U.S. drug spending, or $193 billion, to 29 percent, or $298 billion. Unfortunately, the 2003 *Medicare Modernization Act* prohibits CMS from engaging in drug pricing negotiations. **The AAFP supports policies to ensure Medicare and Medicaid prescription drug programs can best take advantage of recent developments in value-based purchasing so all parts of the U.S. health care system benefit from market-based negotiating efforts to lower drug prices.** Researchers have also concluded the federal government could save $15.2 billion to $16 billion annually if it negotiated with drug manufacturers and achieved the same prices as those paid by Medicaid or the Veterans Health Administration.

Transparency
Transparency policies do not directly lower drug costs but may provide more data that could help federal agencies and policy makers increase accountability. Greater transparency would also allow physicians and patients to make more informed treatment choices. In recent years, public and congressional accountability measures identified that EpiPen had been misclassified as a generic drug for years within the Medicaid Drug Rebate Program. This issue highlights the importance of having strong transparency policies in place. This is reflected in the fact that 30 states have begun to review their own transparency laws. The AAFP supports pricing transparency, including for off-patent and generic drugs.

Six Protected Drug Classes
In 2014, the AAFP opposed a CMS rule that would restrict patients' access to necessary medications. The CMS proposal would have removed antidepressants and antipsychotics from the list of medications that are required to be included in all Part D formularies. Medicare formularies have included six protected drug classes (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection) since 2005, and the AAFP opposes any change to their status that could limit a patient's access to physician-prescribed medications. We recognize there may be noteworthy proposals under consideration that may result in lower costs but urge the Administration to prioritize patient access to these essential drugs.

Thank you for the opportunity to comment on current drug pricing policies. For more information, please contact Sonya Clay, Government Relations Representative, at 202-232-9033 or sclay@aafp.org.

Sincerely,

Michael Munger MD

Michael L. Munger, MD, FAAFP
Board Chair

March 13, 2019

The Honorable Bobby Rush
U.S. House of Representatives
Washington, DC 20515

We are writing to express our support for H.R. 1499, the Protecting Consumer Access to Generic Drugs Act of 2019. The undersigned stakeholders share your commitment to promoting robust generic drug and biosimilar markets that will help reduce prescription drug costs for patients, payers, and taxpayers. We commend you for introducing this important legislation.

Brand and generic drugmakers often enter into agreements that delay the market launch of a generic drug in exchange for financial compensation from the brand company to the generic manufacturer. These settlements can delay for months or years patient access to generic drugs, which can be as much as 90 percent cheaper than the brand version. In recent years, there have also been a number of patent settlement agreements between biosimilar and biologic manufacturers delaying the introduction of lower-cost biosimilars onto the U.S. market.

The Protecting Consumer Access to Generic Drugs Act will promote competition by prohibiting anticompetitive agreements between brand and generic drugmakers. Importantly, the legislation also targets anticompetitive settlements between biologic and biosimilar manufacturers.

Spending on biologic drugs in the United States totaled more than $120 billion in 2017, and approximately two-thirds of drug spending in Medicare Part B is on biologic drugs. With an expected cost discount of 15% to 40% less than originator products, biosimilars create a significant savings opportunity across the U.S. health care system. Enhancing their uptake by preventing anticompetitive settlements between biosimilar and biologic manufacturers is vital to reducing prescription drug costs for American families.

We applaud your commitment to increasing patient access to lower cost, life-saving generics biosimilars, and we look forward to working with you to enact this important legislation into law.

Sincerely,

Cigna,
Community Catalyst,
CVS Health,
Magellan Health,
National Association of Chain Drug Stores (NACDS),
Pharmaceutical Care Management Association (PCMA),
Public Citizen

AMCP | Academy of Managed Care Pharmacy®

February 25, 2019

The Honorable Jim Sensenbrenner
United States House of Representatives
Washington, DC 20510

The Honorable Jerry Nadler
United States House of Representatives
Washington, DC 20510

The Honorable Doug Collins
United States House of Representatives
Washington, DC 20510

The Honorable Peter Welch
United States House of Representatives
Washington, DC 20510

The Honorable David McKinley
United States House of Representatives
Washington, DC 20510

RE: Creating and Restoring Equal Access to Equivalent Samples (CREATES)

Dear Representatives Sensenbrenner, Nadler, Collins, Welch, and McKinley:

On behalf of the Academy of Managed Care Pharmacy (AMCP), I wanted to take this opportunity to express our strong support for H.R. 965, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, bipartisan legislation to increase competition and patient access to safe and affordable generic and biosimilar medicines. AMCP is pleased that you reintroduced the legislation in the 116th Congress on February 5, 2019. We are encouraged that the legislation will again garner bipartisan support and optimistic that with that support the bill will be reported out of the relevant committees to the House floor for consideration.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

As you know, brand name pharmaceutical companies often block generic and biosimilar drug manufacturers from purchasing samples, which are used to conduct the bioequivalence testing necessary in order to file an application for approval with the Food and Drug Administration (FDA). One method that such companies have utilized to stop generic and biosimilar competition is to assert that the Risk Evaluation and Mitigation Strategy (REMS) program allows them to deny samples. In fact, Dr. Scott Gottlieb, FDA Commissioner wrote "We see problems accessing testing samples when branded products are subject to limited distribution . . . in some cases, branded sponsors may use these limited distribution arrangements, whether or not they are REMS – related,

as a basis or blocking generic firms from accessing the testing samples they need. [1] This legislation would strengthen the FDA's efforts to lift barriers to generic drug competition. Secretary Azar recently stated that "we know that certain brand-name manufacturers are abusing the system by blocking access to samples and hiding behind FDA's rules when they do it". [2]

This problem is growing and patient access to safe and affordable generic and biosimilar medication is being unnecessarily delayed. The opposition to this legislation has argued that this legislation will endanger patient safety. It should be noted that generic drug developers are already required to adhere to safe handling and other procedures that protect patient safety, and this applies every time brand companies permit the sale of samples for generic drug development. This legislation would simply close an existing loophole.

With nearly nine out of ten Americans (87%) in favor of "making it easier for generic drugs to come to market in order to increase competition and reduce costs"[3] and 50 health care stakeholders representing diverse interests including AARP (physicians, patients, health plans) calling for congressional action to provide "generic and biosimilar manufacturers a clear and efficient pathway to combat these bad actors,"[4] support for this legislation continues to increase.

To ensure that the practices of a handful of brand companies that prevent generic drug developers from obtaining samples necessary to bring new accessible generic and biosimilar drugs to patients and payors, Congressional action is imperative. The CREATES Act would provide a safe, efficient and targeted pathway to end these abusive, anti-competitive tactics.

Thank you for sponsoring this important legislation. Patients will benefit from your efforts to bring safe and affordable generic and biosimilar medicines to market at the earliest possible date to increase patient access. Please do not hesitate to contact AMCP's Director of Government Affairs, Chris Topoleski at 703-684-2620 or ctopoleski@amcp.org if we can provide additional information.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer

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[1] FDA Voice, FDA Working to Lift Barriers to Generic Competition by Scott Gottlieb, M.D. June 21, 2017. https://blogs.fda.gov/fdavoice/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drug-competition/
[2] Prepared Remarks on Drug Pricing Blueprint by Alex M. Azar II, May 14, 2018. https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html
[3] Kaiser Family Foundation, "Poll: Majorities of Democrats, Republicans and Independents Support Actions to Lower Drug Costs," May 2017.
[4] https://www.csrxp.org/wp-content/uploads/2019/02/FINAL-CREATES-Act-2.5.19.pdf

AMERICAN ACADEMY of DERMATOLOGY | ASSOCIATION

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Washington, DC 20005-2134

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www.aad.org

March 12, 2019

The Honorable Peter Welch (D-VT)
U.S. House of Representatives
2187 Rayburn HOB
Washington, D.C. 20515

The Honorable David McKinley (R-WV)
U.S. House of Representatives
2239 Rayburn HOB
Washington, D.C. 20515

The Honorable David Cicilline (D-RI)
U.S. House of Representatives
2233 Rayburn HOB
Washington, D.C. 20515

Dear Rep. Welch, Rep. McKinley and Rep. Cicilline:

The American Academy of Dermatology Association (Academy), which represents more than 13,800 dermatologists nationwide, is pleased to offer its support for H.R. 985, the "Fair Access for Safe and Timely (FAST) Generics Act," which is intended to promote a more competitive drug market by creating a pathway to expedite generic drugs to market. Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases and many generic disorders. One in four Americans suffers from a skin disease.

The Academy appreciates that H.R. 985 would not only facilitate more affordable drugs to market, but also ensures that safety protocols continue to be held to a high standard and reaffirms the Food & Drug Administration's (FDA) oversight authority in determining safety requirements. Dermatologists are committed to providing the most effective and cost-efficient care and therapies to their patients. Patients suffering from chronic, disabling skin conditions need access to affordable medication that is not only medically necessary, but life-changing and often life-saving. The Academy supports removing barriers to the development and entry of generic drugs in the marketplace, which will increase competition and lower prices of pharmaceuticals.

Dermatology drugs have been disproportionately impacted by rising drug prices. A report published by the Government Accountability Office in August 2016, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases*, noted that while the overall cost of generic drugs has decreased in recent years, there were a few categories of drugs that saw extraordinary price increases. The report highlighted that topical drugs that account for only eight percent of all established drugs represented 46 percent of all extraordinary price increases between 2011 and 2012. When drugs become cost-prohibitive for patients,

they often go without. According to the Centers for Disease Control and Prevention (CDC), "nearly 18% of chronically ill Americans report underusing medications and delaying or not fulfilling therapeutic recommendations because of cost," and "56% of American adults with common chronic diseases self-report nonfulfillment of medication as a result of financial hardship."[1]

The Academy has made patient access to affordable treatments and transparency in drug pricing a top priority. We appreciate your targeted effort to address drug pricing costs by facilitating a more competitive drug market. Please feel free to contact Christine O'Connor, the Academy's Associate Director, Congressional Policy at coconnor@aad.org or (202) 609-6330 if you have any questions or if we can provide additional information.

Sincerely,

George J. Hruza, MD MBA FAAD
President, American Academy of Dermatology Association

[1] Patel MR, Kruger DJ, Cupal S, Zimmerman MA. Effect of Financial Stress and Positive Financial Behaviors on Cost-Related Nonadherence to Health Regimens Among Adults in a Community-Based Setting. Prev Chronic Dis 2016;13:160005.

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March 13, 2019

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Greg Walden
Ranking Member
Committee on Energy and Commerce
United States House of Representatives
2322 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Anna Eshoo
Chairwoman
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Michael C. Burgess
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
2322 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Pallone, Ranking Member Walden, Chairwoman Eshoo, and Ranking Member Burgess:

AARP appreciates your focus on prescription drug prices and the challenges that increasing drug costs pose for seniors, and we thank you for holding this hearing entitled "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition". AARP, with its nearly 38 million members in all 50 States, the District of Columbia, and the U.S. territories, is a nonpartisan, nonprofit, nationwide organization that helps empower people to choose how they live as they age, strengthens communities, and fights for the issues that matter most to families, such as healthcare, employment and income security, retirement planning, affordable utilities and protection from financial abuse.

Prescription drug prices are a high priority for AARP and all older Americans, as older adults are particularly vulnerable to high prescription drug prices. Medicare Part D enrollees take an average of 4.5 prescriptions per month, and over two-thirds have two or more concurrent chronic illnesses. When older Americans talk about the impact of high prescription drug prices, they are often talking about costs that they will face every year for the rest of their lives.

Most Medicare beneficiaries live on modest incomes, with an annual median of just over $26,000. One-quarter have less than $15,000 in savings. This is not a population that has the resources to absorb rapidly escalating prescription drug prices, and many are simply unable to afford the medications they need.

The growing number of brand name and specialty drugs with remarkably high prices – a $100,000 or more – has led many to question whether the costs associated with these products are defensible or sustainable. The timely availability of generic and biosimilar drugs – which will increase competition and help lower prices – will play an important role in addressing these concerns.

We strongly support improving competition by increasing access to generics, including support for two of the bills included in today's hearing: H.R. 965, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, and H.R. 1499, the Protecting Consumer Access to Generic Drugs Act.

H.R. 965, the CREATES Act, targets two forms of anticompetitive behavior that brand name drug manufacturers can use to stifle generic and biosimilar drug entry: refusal to provide access to product samples that are needed to gain FDA approval, and preventing generic and biosimilar manufacturers from joining a distribution protocol applicable to both brand and generic versions of a medicine, or "shared REMS." Providing generic drug manufacturers with a recourse to address these abusive practices will help bring more generic and biosimilar drugs to market.

H.R. 1499, the Protecting Consumer Access to Generic Drugs Act, would ban the use of pay-for-delay agreements. These pay-for-delay agreements provide financial benefits to drug manufacturers at the expense of consumers: the brand-name manufacturer can continue to charge monopoly prices, and the generic company is compensated for its inaction. The Federal Trade Commission (FTC) estimates that pay-for-delay agreements cost American consumers $3.5 billion per year.[1] Generic prescription drugs play an essential role in efforts to reduce health care spending, and AARP believes that additional savings can be found by eliminating pay-for-delay agreements.

We look forward to working with this Committee to enact these two bills as well as other measures that will help lower prescription drug prices and costs for older Americans. If you have any additional questions, feel free to contact me or have your staff contact Amy Kelbick on our Government Affairs staff at akelbick@aarp.org or 202-434-2648.

Sincerely,

David Certner
Legislative Counsel & Legislative Policy Director
Government Affairs

[1] Federal Trade Commission, Pay-for-Delay: When Drug Companies Agree Not to Compete, https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay

Testimony Submitted for the Record

U.S. House Committee on Energy & Commerce Health Subcommittee

Hearing: ""Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"

Lauren Aronson
Executive Director
The Campaign for Sustainable Rx Pricing (CSRxP)

March 13, 2019

Chairwoman Eshoo, Ranking Member Burgess, and members of the House Committee on Energy & Commerce Health Subcommittee, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on lowering the price of prescription drugs by enhancing market competition through reduction in barriers that impede generic drug and biosimilar competition. We very much appreciate your leadership in addressing this critically important issue that American consumers and taxpayers face every day.

CSRxP is a nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that promote competition, transparency, and value to improve affordability while maintaining patient access to innovative prescription drugs that can improve health outcomes and save lives. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and insurance providers.

Prescription drug prices are needlessly high and continue to grow at unsustainable rates. Twenty-three cents of every health care dollar goes toward prescription drugs.[1] One in four Americans cannot afford their medications. Excessively high prices unfairly threaten the financial security, health and wellbeing of U.S. patients and their families every day, as well as strain Federal and state health budgets and the taxpayers who fund them. Too often patients are faced with the unfortunate and unfair choice of purchasing the medications they need to get well and stay healthy and paying their bills. Patients should never be presented with such a choice.

CSRxP thus strongly believes it is imperative to rein in out-of-control drug prices and welcomes the leadership of this Subcommittee in seeking to address this vexing problem that impacts Americans every day. In particular, we firmly believe that significant actions must be taken to address the root cause of the core problem: drug manufacturers – and drug manufacturers alone – set list prices too high and continue to raise them at unsustainably high rates.

CSRxP further believes that meaningful generic and biosimilar competition can place pressure on brand drug makers to lower list prices and reduce overall prescription drug costs. One study funded by the Pharmaceutical Research and Manufacturers of America (PhRMA) found, for example, that prices of oral generic medicines decline by 66 percent in the first 12 months after generic entry and cost 80 percent less than the brands they replace within five years.[2] Those individual product savings from generic

[1] AHIP. "Where Does Your Healthcare Dollar Go?" May 22, 2018.
[2] IMS Institute for Healthcare Informatics. "Price Declines after Branded Medicines Lose Exclusivity in the U.S." January 2016.

competition have reduced prescription drug costs for the U.S. healthcare system in aggregate, saving an estimated $265 billion in 2017 – including more than $80 billion in Medicare and $40 billion in Medicaid – and approximately $1.67 trillion over the last decade.[3] [4] Biosimilars also have the potential to generate substantial savings for consumers and taxpayers, particularly given that they can serve as meaningful competition to many of the high-cost specialty medications that are driving the increased and unsustainable U.S. spending on prescription drugs. One analysis, for instance, projected that the 11 biosimilars already approved for sale in Europe and elsewhere could generate approximately $250 billion in savings over 10 years if they were available in the U.S.[5]

Without significant legislative and administrative action, however, the potential savings for consumers and taxpayers from generics and biosimilars may not be realized. Therefore, CSRxP very much appreciates the Subcommittee's leadership and welcomes actions that will reduce barriers to generic and biosimilar competition. Below we offer our support and comments on many of the pieces of legislation under consideration by the Subcommittee that addresses patent listing barriers, drug development barriers, and market entry barriers to generic and biosimilar competition. In addition, we suggest certain refinements to better ensure that consumers can more quickly access these affordable products and lower their spending on prescription drugs.

CSRxP firmly maintains that without major actions by this Subcommittee and others, the pharmaceutical industry will continue to excessively profit from the anti-competitive and unsustainable pricing practices that make prescription drugs unaffordable and jeopardize access for the patients who need them. We look forward to our continued work with the Subcommittee to reduce barriers to generic and biosimilar competition, to thwart unfair drug company pricing practices, and to implement bipartisan, market-based solutions that curb the unsustainable growth in out-of-control prescription drug prices.

I. Drug Development Barriers

FDA uses the Risk Evaluation Mitigation and Strategy (REMS) program to allow products with potential safety issues to enter the market. When employed effectively and appropriately, REMS improves patient safety and makes accessible medicines that otherwise might not be available due to safety concerns. However, drug manufacturers often engage in abusive, anti-competitive behaviors that manipulate REMS to block generic drug companies from obtaining samples of brand drugs under the guise of addressing patient safety concerns, effectively preventing them from pursuing the research needed to bring less expensive generic drugs to market. Concern exists that manufacturers of reference biologic products have the potential to engage in similar REMS abuses as brand drug makers, causing developers of biosimilar and interchangeable biologics to face similar challenges in obtaining samples of reference biologics for testing.

To thwart this anti-competitive practice by brand manufacturers, CSRxP welcomes the Subcommittee's leadership and urges quick enactment of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act or the Fair Access to Safe and Timely (FAST) Generics Act. Both of these important pieces of bipartisan legislation will help curb REMS abuses and better enable consumers to access more affordable generic drugs more quickly. We urge passage of either of these bills as soon as possible.

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[3] Gottlieb, Scott. "FDA Working to Lift Barriers to Generic Competition." *FDA Voice*. June 21, 2017.
[4] Association for Accessible Medicines. "2018 Generic Drug Access & Savings in the U.S.: Access in Jeopardy."
[5] Express Scripts. "The $250 Billion Potential of Biosimilars." April 23, 2013.

II. Patent Listing Barriers

Rather than only securing a patent for a drug's active ingredient or a biologic's composition of complex molecules, brand drug makers often obtain secondary patents for manufacturing, methods of production, or other aspects of a product to help extend its market exclusivity period and delay consumer access to generic and biosimilar competition. A study of secondary drug patents between 1985 found 2005 concluded that they were highly common, with supplemental formulation patents adding an average of 6.5 years of patent life and method-of-use patents adding an average of 7.4 years of patent life.[6] A separate study of the roughly 100 best-selling drugs between 2005 and 2015 found that, on average, 78 percent of drugs associated with new patents in the FDA's records were existing – not new – drugs coming on the market."[7] For example, Humira, the best-selling pharmaceutical product in the world today with nearly $20 billion in sales in 2018, has over 100 patents and obtained over 70 newer patents in recent years that potentially could extend its market protection as far as 2034, but likely at least through 2022.[8] [9] [10] [11]

Improvements to the Orange Book

Drug manufacturers list patent information in FDA's Orange Book to help generic manufacturers make drug development decisions. Recent research has shown that patent information included in the Orange Book by brand drug makers in certain cases may be of questionable validity or applied inappropriately as a way to delay generic competition.[12] "FDA does not scrutinize the company's representations, however, but merely records whatever the company submits in what is known as the 'Orange Book.' Thereafter, a competitor seeking approval of a generic drug must battle every patent listed in the Orange Book in relation to the drug. Thus, simply listing a patent in the Orange Book can operate to block or delay competition, even if the patent does not cover the drug," the researchers explained.[13] In addition, FDA requires that the drug company submit a short statement describing the approved use (or uses) claimed by the patent, which the agency then assigns a number and lists in the Orange Book as a "use code." Although FDA requires brand manufacturers to submit "use codes," researchers have found that manufacturers in certain instances submit "use codes" that are overbroad or inaccurate, potentially suggesting another means by which to delay generic competition.[14]

Given these potential anti-competitive manipulations of the FDA Orange Book process by brand manufacturers, the Orange Book Transparency Act of 2019 would assist generic drug manufacturers in product development and help remove barriers to generic competition in the marketplace. This

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[6] Feldman, Robin and Wang, Connie. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017.
[7] *Ibid.*
[8] Gonzalez, Richard. "Abbvie Long-Term Strategy." October 30, 2015. Slides 14 - 16.
[9] Pollack, Andrew. "Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions." The New York Times. July 15, 2016.
[10] Slide presentation by Michael Carrier at FTC November 8, 2017 workshop. Slide 48.
[11] AbbVie. "AbbVie Reports Full-Year and Fourth-Quarter 2018 Financial Results." January 25, 2019.
[12] Feldman, Robin and Wang, Connie. "May Your Drug Price Ever Be Green." UC Hastings Research Paper No. 256. October 31, 2017.
[13] *Ibid.*
[14] *Ibid.*

legislation would better ensure that information in the Orange Book is accurate and up-to-date, providing generic manufacturers with improved information to make drug development decisions. In addition to the provisions in H.R. 1503, CSRxP further suggests that FDA work with the U.S. Patent and Trademark Office (USPTO) to increase scrutiny of patents and "use codes" listed in the Orange Book so that patents lists are valid and applied appropriately. This will help guard against any anti-competitive listing of inappropriate or invalid patents of brand drugs by drug makers that delays or prevents generic competition.

Improvements to the Purple Book

FDA's Purple Book includes certain limited information about reference biologics, but not the same level of information as is available for small molecule drugs in FDA's Orange Book. For example, the Purple Book does not include any information related to the patents of brand biological products.[15] Moreover, the limited information available in the Purple Book is not easily accessible and searchable online. Researchers have suggested that lack of sufficient and easily accessible information in the Purple Book has the potential to hinder development and consumer accessibility of biosimilar and interchangeable biological products.[16]

The Purple Book Continuity Act of 2019 would help foster increased development of biosimilar and interchangeable biologics and prevent unnecessarily delayed development and entry of biosimilar and interchangeable biologic products. This legislation would mandate that the Purple Book follow the general format and include information similar to that in the Orange Book, as well as require FDA to publish the Purple Book on its website with routine updates. Indeed, at a minimum, the Purple Book should list, for example, the patents and their expiration dates that protect reference biological products, the dosage, the route of administration, and exclusivity periods (e.g., pediatric and orphan exclusivities) so that manufacturers of biosimilar and interchangeable biologic products can have a better understanding of product development. Moreover, in addition to the provisions included in the legislation, CSRxP further suggests that FDA collaborate with the USPTO to increase scrutiny product patents listed in the Purple Book to limit any potentially invalid or inappropriately applied patents. This will better protect against any anti-competitive tactics by brand biologic manufacturers to delay or prevent competition from interchangeable or biosimilar biologic products through listing of invalid or inappropriate patents.

III. Market Entry Barriers

Prohibition on "Pay-for-Delay" Settlements

Brand and generic drug manufacturers are able to enter into patent dispute settlements – often referred to as "pay-for-delay" settlements – that result in the generic manufacturer agreeing to refrain from marketing its product for a specific period of time in return for compensation (often undisclosed) from the branded company. The Federal Trade Commission (FTC) estimated that these anti-competitive agreements cost consumers and taxpayers $3.5 billion in higher drug costs every year.[17] Of significant concern is that, more recently, these "pay-for-delay" settlements have extended to biologics, delaying

[15] *Ibid.*
[16] *Ibid.*
[17] FTC. "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions." January 2010.

the entry of less costly biosimilars into the market. The Protecting Consumer Access to Generic Drugs Act of 2019 may reduce barriers to generic market entry that result from "pay-for-delay" agreements, improving competition and lowering costs for consumers and taxpayers.

Refining Generic Exclusivity Provisions

CSRxP strongly supports policies that promote increased availability of generic drugs and we welcome the opportunity to work with the Subcommittee on policies that will help expedite the availability of generic drugs to consumers. As Congress considers policies to achieve these goals it is imperative that we increase competition in the prescription drug market and maintain important incentives for manufacturers to develop generic drugs.

Conclusion

In conclusion, CSRxP again thanks the Subcommittee for the opportunity to submit testimony for the record to reduce barriers to generic and biosimilar competition in the U.S. prescription drug marketplace so that can consumers can more quickly access these more affordable medicines. We very much appreciate the leadership from the Subcommittee in addressing this critically important issue that affects American patients and their families every day. CSRxP looks forward to working with the Subcommittee to implementing these and other bipartisan, market-based policies that promote transparency, foster competition, and incentivize value to make prescription drugs more affordable for all consumers while at the same time maintaining access to the treatments that can improve health outcomes and save lives.

Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"
March 13, 2019

Lou Kennedy
CEO and Owner
Nephron Pharmaceuticals

The Honorable Debbie Dingell (D-MI):

1. Ms. Kennedy, as the CEO of a generic drug manufacturer, you are well-aware of the importance of generic competition. Could you describe how more comprehensive patent information in the Orange Book could ensure generics enter the market as soon as possible?

The Orange Book is an important tool we all use to find out where we are in the patent life of a product, and to make sure it is readily available. It is a good tool to promote transparency in pharmaceutical manufacturing.

More competition is definitely good for the consumer and the patient. We all know that free market competition drives prices down. We are usually the sixth or seventh generic to enter the market, and our team is one of those delivering the lowest possible costs to patients. The first two companies to market only save patients around 25 percent because they follow under the Hatch Waxman Act. While this may have worked well at one point in time, it has now become a tool that Big Pharma has used it to keep others out of the market. They allow those first two companies to market to have complete control for the first year, thereby limiting the cost reductions to approximately 25 percent. If you look at the point when other generic manufacturers like Nephron come into the market, we lower the cost to consumers by about 85 percent on average.

2. Ms. Kennedy, you noted Nephron's support for the CREATES Act, which would increase access to branded product samples for generic manufacturers. Could you share more information on how many brand name product samples can be needed throughout the process of creating a generic drug?

It is very important to have access to the reference listed drug – or the brand as it is frequently referred to. That is how we develop the drug to be 100 percent equal in efficacy. In order to have

AB equivalence, and in order to see that the drugs are suitable for the patient and the consumer, we have to do extensive testing on the reference listed drug.

What we do not like to see, and what most of the Big Pharma companies exercise, is any possible loophole in the law to keep generic manufacturers, like Nephron, from getting access to the reference listed drug. There are a variety of games that are played to exclude us, and it only hurts the American patient and costs us valuable time in lowering the cost.

The Honorable Michael C. Burgess, M.D. (R-TX):

1. It appears that Nephron pharmaceuticals has a number of drugs that have been in shortage in recent years. Is there any action that you would recommend Congress consider to address drug shortages?

Under the very wise leadership of FDA Commissioner Scott Gottlieb, a program was started to offer a 10-month expedited review for any generic that is being submitted to the FDA on the drug shortage list. It is an excellent program, and it should be continued in perpetuity. While it only gives expedited review to the first three applicants to file, in doing so, it inspires all of us to work quickly for patients through development and start the submission process. It is critical to be counted as the first three so we can get these generics to market.

But the real answer to solving drug shortage is being able to put these drugs, if they are compatible, into plastic containers instead of glass, using blow fill seal (BFS) technology. That is what our company is on the forefront of doing.

It is important for Congress to be open to allowing companies like ours to show the FDA how we can use this kind of plastic technology for high throughput manufacturing. Right now, glass is in short supply. Plastic is more available. During the pandemic, glass has been an even tighter supply problem. If we are going to stick with the current pace of glass approvals, we should make sure we increase the ability to get more medical grade glass to the generic drug makers. It would allow us to get more drugs on shortage out to patients.

Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"
March 13, 2019

Anthony Barrueta
Senior Vice President, Government Relations
Kaiser Permanente

The Honorable Debbie Dingell (D-MI):

1. **Mr. Barrueta, sometimes there are generic drugs or biosimilars that are already approved and on the market, but are not being fully utilized. You mentioned that other providers have been slow to transition to biosimilars compared to Kaiser Permanente. Could you explain why there has been this delay among certain providers?**

Within our integrated health care delivery system, Kaiser Permanente[1] successfully uses biosimilars to improve affordability for patients while maintaining or improving quality of care, saving our system millions of dollars in the process. We embraced the first FDA-approved biosimilar, Zarxio® (filgrastim-sndz), and now use it instead of Neupogen® (filgrastim) in approximately 95 percent of cases. We replicated this success with Inflectra® (infliximab-dyyb), which we use more than 80 percent of the time instead of Remicade® (infliximab). In the rest of the market, Inflectra® and Zarxio® utilization hover around 3.2 percent and 31.7 percent, respectively.[2] In late 2019 and early 2020, we launched new initiatives to adopt three additional biosimilars: Truxima® (rituximab-abbs), Kanjinti® (trastuzumab-anns) and Mvasi® (bevacizumab-awwb). Our adoption rates already exceed 90 percent for each of these products.

Our approach to biosimilars is rooted in strong collaboration between our pharmacists and the Permanente Medical Group (PMG) physicians. We maintain a primarily internalized pharmacy system staffed by over 14,000 pharmacy personnel that empowers us to coordinate drug purchasing, evidence reviews, and dissemination of unbiased information across our system. Our clinical colleagues also establish and manage formularies and develop treatment guidelines they

[1] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 650 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members. Our mission is to provide high-quality, affordable care and improve the health of our members and communities we serve.

[2] IQVIA Data Show Biosimilars Struggling for Market Share in the U.S. (February 2019). *Journal of Clinical Pathways*. Available at: https://www.journalofclinicalpathways.com/news/iqvia-data-show-biosimilars-struggling-market-share-us.

use to govern their practices through a rigorous, evidence-driven process. On an ongoing basis, our pharmacists review and develop objective analyses of drugs that are reviewed by our clinician-led Pharmacy & Therapeutics (P&T) committees. Prescribers within our system have confidence in the integrity of our formularies because they are grounded in evidence with the input and oversight of their expert peer colleagues. This confidence extends to our recommendations and guidelines on biosimilars.

Kaiser Permanente is also committed to generating and disseminating unbiased information and data about biosimilars to support treatment decisions within our system. We make substantial resources available to whole care teams, such as bulletins, webinars, presentations, and a team of Drug Education Coordinator pharmacists who can answer specific questions. Our prescribers are also relatively insulated from pharmaceutical industry marketing practices that can discourage biosimilar use due to the steps the PMG physicians and our pharmacy organization take to govern and limit sales representative access to our physicians and care teams.

Critically, our providers also have no financial incentive to choose any specific drug, regardless of the patient's type of coverage. PMG physicians contract exclusively with Kaiser Foundation Health Plans and are paid on a salary basis that is not dependent on the acquisition cost of drugs administered. This lack of financial incentives related to drug selection facilitates financially neutral prescribing based on evidence.

Kaiser Permanente may have some advantages as an integrated health care delivery system with respect to biosimilar uptake. Most notably, many organizations do not have an integrated pharmacy capable of fully coordinating biosimilar initiatives with providers and health plans. We strongly believe, however, that there are steps policymakers can take to support other providers in boosting biosimilar use:

- Some manufacturers engage in marketing campaigns that suggest biosimilars are inferior to reference products. There are few unbiased resources about biosimilars that are readily available to prescribers to counter this misleading narrative. Policymakers could increase access to unbiased evidence about biosimilars to help instill confidence in both clinicians and patients. For example, HHS could convene non-conflicted experts to provide product-specific counter-detailing and develop patient- and provider-friendly resources with accurate information about biosimilars, similar to what occurs within our system.
- Converting patients from reference products and overcoming other operational barriers to using biosimilars can be resource intensive. Policymakers may need to provide temporary support to encourage providers to take these steps until a greater level of expertise with biosimilars is achieved. Bolstering add-on payments for biosimilars under Medicare Part B and shared savings models are options that Congress should explore further.
- Potentially perverse payment incentives that may encourage providers and health plans to prefer more expensive reference biologics over biosimilars warrant further examination.

We outline best practices and recommendations in greater detail in the attached comment letter on FDA's 2018 *Biosimilars Action Plan*. We would be happy to discuss our experience with biosimilars further.

KAISER PERMANENTE®

September 21, 2018

Dr. Scott Gottlieb
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Room 600E
Silver Spring, MD 20993

Submitted electronically to: www.regulations.gov

RE: ***Facilitating Competition and Innovation in the Biological Products Marketplace*** **(Docket No. FDA-2018-N-2689-0001)**

Dear Commissioner Gottlieb:

Kaiser Permanente appreciates the opportunity to respond to the U.S. Food and Drug Administration's (FDA) request for comments on *Facilitating Competition and Innovation in the Biological Products Marketplace*. We commend FDA's continued focus on increasing biosimilar competition, including through the recent release of the *Biosimilars Action Plan*.

Kaiser Permanente is committed to providing high-quality, affordable care and improving the health of our members and communities we serve. As the largest private integrated health care delivery system in the United States, the Kaiser Permanente Medical Care Program delivers health care to more than 12.2 million members in eight states and the District of Columbia. Within that footprint, we maintain an internalized pharmacy system, including 395 out-patient and 39 inpatient pharmacies, 90 clinic-administered drug sites, and 27 call center and central fill facilities, staffed by over 15,500 pharmacists and staff. In 2016, Kaiser Permanente administered 44 million inpatient doses of prescription drugs, and 10.6 million doses through our outpatient clinics. In 2017, our out-patient pharmacies dispensed 90 million prescriptions. Kaiser Permanente's current total drug spend is over $8 billion annually.

Kaiser Permanente leads the market in biosimilar utilization, due to a strong commitment across our integrated system to providing both our members and employees with balanced, evidence-based information about the medications we prescribe. We are eager to share best practices from our efforts to facilitate clinically appropriate use of biosimilars in the few cases where they are available to patients. Major contributors to Kaiser Permanente's success include:

- Strong prescriber confidence in our physician-led and evidence-driven formulary;
- Permanente physician and care team commitment to open communication and partnership with our members in prescribing decisions;
- Our ability as an integrated system to leverage, generate, and disseminate robust clinical data demonstrating biosimilar safety, efficacy, and value;
- A culture of sharing biosimilar success stories within care teams and from physician-to-physician; and

- Internal policies that significantly restrict marketing and detailing by pharmaceutical companies in our facilities and to Permanente physicians.

Despite our success at encouraging biosimilar utilization where possible, we remain deeply concerned about the burden of unsustainably high biological product prices on our members. Biological products and specialty drugs are the fastest growing component of prescription drug spending. Treatment costs for some biologics can be hundreds of thousands of dollars per year, imposing crippling costs on patients, the health care system, and the government. Fostering a robust market for biosimilar competition is essential to reducing the burden of high drug prices. We applaud FDA for addressing this important issue and look forward to working with you as this initiative moves forward.

I. Facilitating the Development of Biosimilar & Interchangeable Products

Interchangeability
Kaiser Permanente supports FDA's efforts to facilitate the development of interchangeable products. Fostering a strong market for biosimilars holds promise for increasing competition and reducing the burden of high drug prices, especially where biosimilars are designated interchangeable. To be interchangeable, a biosimilar must demonstrate that it produces the same clinical result as the reference product in any given patient. When a biosimilar satisfies that high standard, the law should not create arbitrary barriers to substitution. Even in cases where a biosimilar is not interchangeable, laws and policies should not deter physicians from using their clinical expertise and discretion to prescribe a biosimilar. Indeed, the success of generic competition in the small molecule market is attributable in part to the efficient substitution and the unencumbered ability of physicians to prescribe effective, more affordable generics.

To date, there are no licensed[1] interchangeable biosimilars in the United States. Until there are clear standards on how biosimilar manufacturers can obtain interchangeability designations, cost savings to patients and the health care system from increased biosimilar development will not reach their full potential. FDA should do more to create certainty and predictability for biosimilar manufacturers seeking interchangeability designations, while still ensuring that such determinations are guided by high scientific standards. One way to give manufacturers the certainty necessary to invest in developing such products would be to finalize the draft guidance on the factors FDA will consider in making interchangeability determinations. Such certainty will promote increased competition and lower costs.

Biosimilar Development & FDA Review
FDA should take steps to facilitate efficient biosimilar development and licensing, through improved clarity on submissions and increased agency communications with biosimilar manufacturers throughout the review process. FDA plays an important role in promoting timely biosimilar competition, including regulatory review to ensure requirements are as efficient as

[1] "Licensed" is technically the appropriate term to use for biosimilars under a Biologic License Application (BLA) instead of "approved" (approved is the correct term for a New Drug Application (NDA) and an Abbreviated New Drug Application (ANDA). We use the terms interchangeably throughout because in some cases we refer to both NDAs and BLAs.

possible without compromising safety and efficacy standards. Submissions demonstrating biosimilarity should not require the same rigor as "safety, purity, and potency"[2] or "safety and efficacy"[3] demonstrations for reference products. The use of expedited approval methods such as surrogate endpoints, biomarkers, or more efficient clinical trial designs may be appropriate tools to demonstrate biosimilarity, they may also facilitate investment in development.

Biosimilarity, however, is a more complex demonstration than bioequivalency, which is the required showing to approve generic drugs through Abbreviated New Drug Applications (ANDAs). Thus, more evidence demonstrating biosimilarity will be needed to successfully encourage prescribing and inform formulary development than what is sufficient for small molecule generics. Kaiser Permanente's physician- and pharmacist-led formulary development process relies on access to robust data from FDA and other sources. our physicians choose to prescribe from our formulary in an overwhelming majority of cases, because it is developed by their peers, based on ample evidence. Access to data is crucial to enable us to instill confidence in biosimilars among prescribers, which in turn increases patient confidence and utilization.

Due to the importance of clinical evidence in guiding biosimilar prescribing decisions, we encourage FDA to carefully balance efforts to streamline biosimilar review against the need for quality data in manufacturer submissions. We agree it is sometimes appropriate for FDA to allow flexibility and use of expedited methods in submissions, including in some cases when there are few alternatives to a high-price reference product. Biosimilars also should never be held to a higher standard of review than reference products. However, surrogate endpoints and biomarkers merely predict clinical outcomes – they do not provide a full risk-benefit profile for a drug. As a result, they leave gaps in information about how a drug will perform in real-world clinical settings that reduce physician confidence in prescribing decisions and sometimes lead to downstream complications in care.

A condition for approvals that are based on expedited methods should be the timely completion of Phase IV post-market studies, regardless of whether the drug at issue is a biosimilar, reference product, or small molecule drug. Phase IV studies are critical to understanding drug safety and effectiveness outside the narrow confines of clinical trials. Pharmaceutical companies often fail to conduct these studies even when they are required. A study in the *New England Journal of Medicine* found that among over 600 post-market studies mandated in 2009 and 2010, 20 percent were never started, while others were significantly delayed.[4] These failures on the part of pharmaceutical companies deprive physicians and pharmacists of vital information that can help improve patient outcomes and avoid adverse medical events.

Kaiser Permanente also supports FDA's interest in learning about best practices from the European Medicines Agency (EMA), which has greater experience with biosimilar approval and uptake. Europe has been more successful than the United States at fostering the right market conditions for biosimilar development, while still maintaining high scientific standards. Intellectual property laws in the United States create unique barriers to competition;

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[2] BLA licensing standard
[3] NDA approval standard
[4] Woloshin, S. et al. (September 2017). The Fate of FDA Postapproval Studies. *New England Journal of Medicine*. Available at: https://www.nejm.org/doi/full/10.1056/NEJMp1705800

nevertheless, FDA may be able to learn valuable lessons from EMA's approach to biosimilars. EMA has approved over 40 biosimilars.[5] By comparison, FDA has licensed 12 biosimilars, most of which are not yet available to patients due to patent disputes.[6] As a result, patients in Europe have significantly more choices and affordable options than patients seeking the same care in the United States. We encourage FDA to reach out to EMA to start a dialogue, with the goal of identifying practices FDA could adopt to move our domestic biosimilar market forward.

Real World Data & Evidence

Kaiser Permanente appreciates FDA's interest in use of real world data and evidence to support appropriate prescribing and post-market safety assessments of biosimilars. FDA defines real world evidence as "information on health care that is derived from multiple sources outside typical clinical research settings, including electronic health records, claims and billing data, product and disease registries, and data gathered through personal devices and health applications."[7] Premarket use of real world evidence raises evidentiary concerns, since real world data is generally observational and non-randomized. Increased use of real world data in post-market contexts, however, could help uncover important information about product use by a larger, more diverse population in uncontrolled settings over a longer period than clinical trials.

Kaiser Permanente has successfully used real world data to build confidence in biosimilar prescribing among Permanente physicians. Our integrated structure enables us to harness the power of real world data to support conversions from reference products to biosimilars across our system. For example, our surveillance of patient switches from Remicade® to the biosimilar Inflectra® and from Neupogen® to the biosimilar Zarxio® provided concrete evidence of positive patient outcomes, demonstrating to prescribers that these conversions can be accomplished without changes in safety and efficacy. Our Drug Information Services (DIS) department (specifically, the Pharmacy Outcomes Research Group within DIS) frequently analyzes real world data related to drugs.

Based on our success using real world data within our system, we suggest FDA actively promote the value these data as another reliable and robust source of information to support biosimilar conversions.

We also support FDA's efforts to partner with private insurers to move toward a more unified and proactive system for drug safety monitoring, including for biological products and biosimilars. Kaiser Permanente already uses real world data to provide critical real-time safety and effectiveness information across our system. For example, our clinical databases were the first to detect serious risk of heart attack and cardiac death associated with Vioxx, a widely used arthritis and pain drug that was ultimately pulled from the market.[8] We were proud to partner with FDA to uncover Vioxx safety concerns and reveal them to the public. Kaiser Permanente is

[5] Biosimilars Approved in Europe (August 2018). Generics and Biosimilars Initiative. Available at: http://www.gabionline.net/Biosimilars/General/Biosimilars-approved-in-Europe
[6] Biosimilar Product Information. FDA. Available at: https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm580432.htm
[7] Sherman, R. et al. (December 2016). Real-World Evidence—What Is It and What Can It Tell Us?. *New England Journal of Medicine*. Available at: https://www.nejm.org/doi/full/10.1056/NEJMsb1609216
[8] FDA Releases Memo on Vioxx. (November 2004). *New York Times*. Available at: https://www.nytimes.com/2004/11/03/business/fda-releases-memo-on-vioxx.html

also a collaborating institution in the Sentinel Initiative, FDA's national electronic system for proactively monitoring drug safety. We look forward to learning more about FDA's plans to enhance use of Sentinel and other data from private insurers in the context of biosimilars.

II. Increasing Provider & Patient Understanding of Biologics & Biosimilars

Provider & Patient Education

Kaiser Permanente appreciates FDA's interest in enhancing provider and patient education about biosimilars, which is a high priority for our Permanente Medical Groups and pharmacy business. Our success at encouraging clinically appropriate use of biosimilars within our system is in large part attributable to physician confidence in our formulary, which is developed by Permanente physicians alongside our pharmacy experts and relies heavily on access to clinical data. Educational efforts involving the whole care team and a culture of sharing patient stories are also critical components of Kaiser Permanente's success with biosimilars to date.

Timely access to data is crucial to Kaiser Permanente's formulary development process and helping providers evaluate when biosimilars are appropriate for their patients. We appreciate FDA's efforts to make more information about biosimilars, including review materials, available to the public through its website. The relatively robust data for both Inflectra (biosimilar for Remicade) and Zarxio (biosimilar for Neupogen) provided the information our physicians and pharmacists needed to evaluate whether switches were appropriate for individual patients. Unfortunately, review materials are not always made public, particularly when the product is not subject to Advisory Committee review or is not the first licensed biosimilar in its class. Even when such resources are public, posting is often delayed, sometimes by over a year. FDA should strive to make review materials for all licensed biosimilars available on its website within two months of approval.

Kaiser Permanente's success with biosimilar utilization also reflects a concerted effort across our system to provide reliable, evidence-based information about biosimilars to prescribers and care teams. We maintain a team of drug information pharmacists to answer physician questions and disseminate information about biosimilars and other drugs through bulletins, webinars, and presentations. These resources give our prescribers the tools and information necessary to appropriately switch patients onto biosimilars; they were used for conversions to Inflectra and Zarxio.

Our experience creating educational tools and resources for prescribing biosimilars suggests that prescribers would benefit from FDA-developed tools and resources on biosimilars, especially if these tools are made available in a flexible manner that accommodates busy schedules. Many physicians and health care professionals struggle to find time to participate in educational activities. Kaiser Permanente strongly supports FDA's proposal to make biosimilar webinars and other educational activities developed by the agency eligible for Continuing Education (CE) or Continuing Medical Education (CME) credit whenever possible to increase participation.

While clinical data is essential to biosimilar education across our system, a culture that promotes sharing meaningful prescriber experiences and patient stories is equally important for building prescriber confidence. Permanente physicians and our other health care professionals greatly

appreciate learning from the experiences of their colleagues, whom they know, trust, and respect. FDA should consider collecting and disseminating patient stories, in a manner that protects patient privacy and confidentially.

FDA should ensure that biosimilar education efforts include the entire care team—physicians, nurses, pharmacists, physician assistants, and other health care professionals. Many biological products and biosimilars are infusions or injections administered by nurses, who discuss these medications with patients and answer their questions on a regular basis. FDA should design educational materials and campaigns with a broad range of health care professionals in mind.

Most importantly, more must be done to increase patient confidence in biosimilars. No patient wants to feel like she is receiving an "inferior" medicine for her condition. Unfortunately, these misperceptions about biosimilar products are common (*See* "Reducing Misinformation about Biosimilars" section). Because providers are a trusted resource for patients, improving prescriber education about biosimilars should also enhance patient education and comfort. FDA can help by continuing to aggressively use its platform to assure the public that biosimilars are safe and effective alternatives to reference products, including through consumer-focused statements and public awareness campaigns.

Reducing Misinformation about Biosimilars

Kaiser Permanente is concerned that efforts to provide incomplete or misleading information about biosimilars reduce prescriber and patient confidence in safe and effective products. Because biosimilars are not identical to reference products, it is possible that a biosimilar may not always be the right choice for an individual patient. However, some reference product manufacturers have greatly exaggerated the risks and differences between products, ignoring legal requirements that biosimilars have "no clinically meaningful differences" from the reference product[9] or suggesting that a switch is only safe if the biosimilar is interchangeable. These misinformation campaigns attempt to interfere with prescribing decisions that should be based on clinical evidence and the patient's individual needs.

Reference product manufacturers use a variety of tactics to create doubt about biosimilars. For example, the manufacturer of the reference product Remicade has been disseminating a patient brochure cautioning against switching to the biosimilar Inflectra, because FDA has not deemed it interchangeable, despite evidence that switching does not reduce safety or efficacy. Online and social media campaigns undertaken by various manufacturers also characterize biosimilar use as risky (in one case, through an online video cautioning patients that switching is not a good idea if their medicines are working). These misleading claims have also been used by reference product manufacturers and third-party groups they fund to influence state and federal policies, including guidance on biosimilar naming conventions and state substitution laws.[10]

Kaiser Permanente is relatively insulated from these misinformation campaigns because our internal policies greatly restrict marketing and detailing by pharmaceutical companies in our facilities and to Permanente physicians. We generally limit detailing to formulary products and

[9] 42 USC § 262(i)(2)(A)
[10] Pfizer Inc. (August 2018). Citizen Petition to FDA. Available at: https://www.bigmoleculewatch.com/wp-content/uploads/2018/08/Citizen_Petition_from_Pfizer.pdf

audit detailing content when it is allowed within our system. Kaiser Permanente also goes to great lengths to ensure that our prescribers have access to other reliable sources of robust, unbiased information about drug products. As a result, our prescribers have less need to rely solely on information provided by the pharmaceutical industry.

While we have been able to mitigate their effect within our system, we remain concerned that these campaigns have polluted the overall information environment about biosimilars. We are particularly concerned about campaigns targeting patients. FDA should consider how it can encourage other health care system stakeholders to access reliable information about biosimilars from sources other than the pharmaceutical industry, including by adopting counter-detailing policies or similar detailing restrictions to Kaiser Permanente. FDA should also explore how current law could be used to prohibit false and misleading claims about biosimilars by reference product manufacturers.

III. Supporting Market Competition

Exclusivity

Kaiser Permanente believes FDA should avoid interpreting current law to expand exclusivity for reference biologics, causing further delay of more affordable, badly needed biosimilar options for patients. The 12-year exclusivity period under the *Biologics Price Competition and Innovation Act* (BPCIA) (Pub. L. 111-148) already delays biosimilar competition for too long, harming patients and resulting in billions of dollars in lost savings for taxpayers.[11] Even seemingly incremental expansions of exclusivity could be subject to abuse and gaming by pharmaceutical companies looking to block access to competing therapies.

Moving forward, we encourage FDA to take bold action to ensure that exclusivity incentives reward meaningful innovation, advancements in clinical care, and investments in therapeutic areas that would otherwise be neglected. Too often, these incentives are abused by the pharmaceutical industry to maintain high prices and monopolies without clinically meaningful improvements or innovation. Kaiser Permanente is encouraged that Commissioner Gottlieb acknowledges these problems and the need to ensure exclusivity provides "the right incentives."[12] As prices for biological products continue to climb, FDA should work with Congress to reassess the costs and benefits of exclusivity incentives to ensure an appropriate balance between innovation and affordability.

Any review of exclusivity by FDA or Congress should also include the *Orphan Drug Act* (Pub. L. 97-414), which provides seven additional years of exclusivity for rare indications. Many biological products, which already enjoy 12 years of exclusivity, have orphan designations. The *Orphan Drug Act* intended to reward drug manufacturers for developing treatments for rare disease – an investment that otherwise would not be economically viable. Over the years, however, orphan drugs have become major revenue producers, which has led to abuse of the law's original intent. Pharmaceutical companies sometimes seek orphan designations for drugs

[11] Policy Proposal: Reducing the Exclusivity Period for Biological Products, PEW Charitable Trusts, available at: http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2017/09/policy-proposal-reducing-the-exclusivity-period-for-biological-products

[12] Tribble, S. (December 2017). FDA Commissioner: Are the Incentives Right for Orphan Drugs? NPR. Available at: https://www.npr.org/sections/health-shots/2017/12/22/572673636/fda-commissioner-are-the-incentives-right-for-orphan-drugs

already on the market, or tailor indications to overly narrow populations when the drug is typically used to treat common conditions. Due in part to these tactics, numerous drugs now benefit from orphan exclusivity. In 2016, 41 percent of new approvals included an orphan designation.[13] The fact that Humira®, the world's best-selling drug, was granted orphan status illustrates the perverse abuses of this well-intentioned law.

Post-Licensing Delays in Biosimilar Market Entry

Kaiser Permanente greatly appreciates FDA's interest in addressing the lag time between biosimilar licensing and marketing. FDA has licensed 12 biosimilars to date; only four are available to patients.[14] Patent disputes appear to be the primary cause of delays.

For example, reference product manufacturers often hold numerous patents for the same biologic and can use that to their advantage in disputes with biosimilar manufacturers (e.g., the settlement agreement over 61 potential patent breaches associated with Amjevita®, a biosimilar version of Humira. Humira is protected by over 100 patents, ranging from attributes of the product to manufacturing processes). This complex web of patents, often referred to as a "patent estate" or "patent thicket," gives the reference product manufacturer considerable leverage in settlement negotiations, because it is virtually impossible to manufacture the related biosimilar without breaching multiple patents. So even though FDA licensed Amjevita in 2016, its manufacturer agreed to delay market entry until 2023 and will even pay Humira's manufacturer royalties on Amjevita sales upon marketing.[15] Other manufacturers developing Humira biosimilars are engaged in similar negotiations, also delaying entry of those products until 2023. Other brand-name companies are now trying to replicate the Humira strategy on their own biological products, which suggests an alarming trend.[16]

While patent settlements are outside FDA's direct purview, we strongly encourage the Agency to fully inform the Federal Trade Commission (FTC) and Congress to enable them to thoroughly review settlement agreements between reference product and biosimilar manufacturers for potential anticompetitive behavior. FDA should also explore how agency processes could be leveraged to help biosimilar manufacturers navigate potential disputes and challenges, such as by requiring more detailed disclosures of patents and manufacturing processes by reference product manufacturers. To the extent that such information could be shared with biosimilar manufacturers in the early stages of development, it may help companies anticipate and overcome obstacles to market entry.

REMS Abuses

Kaiser Permanente supports FDA's efforts to address abuses of Risk Evaluation and Mitigation Strategies (REMS). As part of REMS programs, FDA can require "elements to assure safe

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[13] Kesselheim, A. et al. (2017). Determinants of Market Exclusivity for Prescription Drugs in the United States. *JAMA*. at: https://www.ncbi.nlm.nih.gov/pubmed/28892528

[14] Biosimilar Product Information. FDA. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580432.htm

[15] Berkrot, B. (September 2017). AbbVie, Amgen Settlement Sets Humira U.S. Biosimilar Launch for 2023. *Reuters*. Available at: https://www.reuters.com/article/us-abbvie-amgen-humira/abbvie-amgen-settlement-sets-humira-u-s-biosimilar-launch-for-2023-idUSKCN1C32G5

[16] Koons, C. (September 2017). This Shield of Patents Protects the World's Best-Selling Drug. *Bloomberg Businessweek*. Available at: https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug

usage" (ETASU), such as special certification for dispensing, prescriber training, and dispensing limited to certain health care settings. ETASU requirements are sometimes leveraged by pharmaceutical companies to restrict a drug's distribution by erecting barriers to market entry that do not result in safety benefits for patients. While we strongly support the REMS program's goal of improving safety, the program must be updated to ensure pharmaceutical companies cannot game the process to block biosimilar competition or artificially restrict distribution pathways to maintain unreasonably high prices.

Biosimilar manufacturers often seek access to samples of reference products to conduct studies to demonstrate biosimiliarity and interchangeability to FDA. Some brand-name pharmaceutical companies use REMS to justify withholding samples, causing delays in competition. Recently, FDA posted a list of brand-name drugs where a request for access to a sample for generic development was blocked, revealing over 50 medicines for which generic alternatives have been delayed due to REMS abuses.[17] To resolve this problem, Kaiser Permanente supports the *Creating and Restoring Equal Access To Equivalent Samples Act* (CREATES Act) (S. 974/H.R. 2212), which establishes a cause of action against companies that fail to provide samples on reasonable terms. The nonpartisan Congressional Budget Office (CBO) estimated that the CREATES Act would reduce federal health spending by $3.8 billion over ten years. Private payers would also save significantly. In the absence of a legislative fix, we encourage FDA to exercise all authority it has over the REMS program to curb abuses.

Brand-name companies also use REMS to enter into restrictive contracting arrangements that make it impossible for providers and pharmacies to acquire drugs at a reasonable price. Many of the drugs subject to these arrangements are biological products. Some companies have used ETASU requirements to contract exclusively with a limited number of specialty pharmacies, protecting high prices by controlling access to their products. Even though Kaiser Permanente's National Specialty Pharmacy has extensive experience complying with REMS and ETASU requirements, many pharmaceutical companies do not allow us to acquire and dispense restricted drugs within our system. Not only do these restrictions allow companies to burden patients with higher prices, they also inhibit the ability of integrated health systems to implement safety checks, monitor quality, and coordinate care when information related to the REMS drug will not be automatically included in the patient's electronic health records and our pharmacy systems because valuable prescribing information is held outside our system.

Kaiser Permanente recommends that REMS explicitly permit health systems or pharmacies that can demonstrate they meet or exceed REMS requirements to access and dispense REMS drugs. Therefore, we support new FDA guidance or regulations clarifying that REMS programs cannot arbitrarily restrict distribution. These modifications would help facilitate lower drug costs through competitive pricing and national purchasing negotiations. It would also leverage existing systems and tools designed to enhance patient safety and continuity of care.

FDA-FTC Collaboration Against Anticompetitive Behavior

[17] Reference Listed Drug (RLD) Access Inquiries. FDA. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm

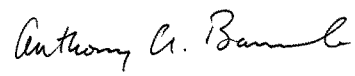
Kaiser Permanente supports FDA's interest in working with the Federal Trade Commission (FTC) to increase competition in biological product markets. Further coordination between FDA and FTC would foster greater understanding about how FDA processes are abused for anticompetitive purposes. At the recent public meeting on biosimilars, FDA recognized FTC as a "vital partner" in the Agency's work on competition.[18] FTC has also made clear it is willing to partner with HHS to make pharmaceutical markets more competitive, identifying biosimilar naming, REMS abuses, and interchangeability as areas of interest.[19]

In addition to the topics FTC already identified, we encourage FDA and FTC to jointly review exclusivity, settlements between reference product and biosimilar manufacturers, product hopping and evergreening through "biobetter" reformulations, abuse of citizen petitions, and misleading communications about biosimilars by reference product manufacturers. The agencies should also issue public reports to share their findings with outside stakeholders and experts.

* * *

Kaiser Permanente appreciates the opportunity to provide feedback in response to FDA's request for comments. We would be pleased to discuss these comments and our experience with biosimilar and biological products in our integrated delivery system. If you have questions, please contact me (510.271.6835; anthony.barrueta@kp.org), Laird Burnett (202.216.1900; laird.burnett@kp.org), or Polly Webster (202.216.1900; polly.f.webster@kp.org).

Sincerely,



Anthony A. Barrueta
Senior Vice President, Government Relations

[18] Remarks by Scott Gottlieb, M.D. (September 2018). Public Meeting on Facilitating Competition and Innovation in the Biological Products Marketplace. FDA. Available at: https://www.fda.gov/NewsEvents/Speeches/ucm619277.htm
[19] Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. (July 2018). FTC. Available at: https://www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-department-health-human-services-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs.pdf

Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"
March 13, 2019

Jeff Kushan
Partner
Sidley Austin LLP

The Honorable Bill Flores (R-TX):

Patents are critically important for developing FDA-approved biopharmaceutical products. Unlike companies in other sections, biopharmaceutical companies are not immediately able to capitalize on the value of their patents. As recognition of these unique circumstances, Congress established a separate dispute resolution framework for approved drugs and biologics. In 1986, Senator Hatch and Representative Waxman crafted the Hatch-Waxman Act to carefully balance incentives for both pharmaceutical innovation and drug affordability. As a result, today, 9 out of every 10 prescriptions in the U.S. are generic drugs. Now Americans have access to more affordable medicines than ever before. Simply put, the law has been a success.

It was a success until 2012 when Congress passed the America Invents Act (AIA), which established new patent office trial proceedings- Inter Partes review (IPR) and Post Grant Review (PGR) to combat patent litigation abuse by trolls. Both Senators Grassley and Schumer acknowledge that the AIA was not drafted with the pharmaceutical industry in mind.

Due to this unintentional oversight, not only have IPRs been used to circumvent Hatch-Waxman Act and BPCIA, but hedge funds have brought bogus IPR challenges against pharmaceutical patents in order to short-sell the stock and manipulate the market to their advantage.

Furthermore, according to an NYU Journal of Intellectual Property and Entertainment Law article titled: Disrupting the Balance: The Conflict Between Hatch-Waxman and inter partes review:

A patent challenger who is taking full advantage of the Hatch-Waxman system can nonetheless pursue a parallel IPR proceeding even while engaging in Hatch-Waxman litigation. This essentially turns the IPR process into a form of venue shopping. The result of these duplicative proceedings can "undo" prior Hatch-Waxman court decisions based on full trial

records. Unique to the biopharmaceutical space, the two different tribunals give challengers two opportunities invalidate drug patents.

1. Mr. Kushan, is it fair to characterize smaller biotech companies and startup companies as vulnerable under the current dual-track scheme because they do not have the resources to defend their patents in both settings?

Response: Generally, yes. While all biotechnology companies face significant hurdles in bringing their innovative pharmaceutical products and therapies to market, those obstacles are more pronounced for smaller companies.

As an initial matter, scientific uncertainties prevent many promising products and technologies from ever reaching the market. Another major obstacle is securing the capital needed to support research as well as the pre-clinical and clinical phases of the drug development process. Larger companies have access to capital from existing revenue as well as capital markets. Smaller companies, however, are dependent on attracting capital from private investors. To induce those investments, these companies must be able offer the prospect of significant commercial success of their products. That, in turn, requires those products to enjoy an effective period of market exclusivity if and when they eventually reach the market.

A primary mechanism for providing the market exclusivity for these products is the patent system. Patents, however, must be pursued well-before the products ever reach the market. Those early patents are what the smaller companies identify as the legal mechanism they have to protect the private investments needed to develop their new products and bring them to market. Permitting early challenges to these patents increases the possibility that these innovators will not be able to use their patents when they are needed—when a generic seeks to enter the market. Permitting early and parallel challenges to patents thus introduce uncertainty which erodes the incentive these patents are designed to provide. Unfortunately, the impact of that uncertainty is felt primarily by the smaller biotechnology companies that are dependent on private sector investments to fund their product development.

2. And to that end, Mr. Kushan, why is it that we need both tracks running at the same time? Can't IPR be characterized as hindering pharmaceutical innovation?

   Some of us believe that the dual tracks of invalidating a drug patent produce significant uncertainty for manufacturers. The AIA also exacerbates pricing pressure on brand companies, who now need to factor the insurmountable risk into their list price. Drug companies know that parties get a second bite at the apple by challenging their drug patent in both tribunals.

Response: There is no need for two parallel systems for challenging the key patents on new drug products. In fact, the very design of the Hatch-Waxman system assumes that patent challenges will only occur at a time when generic drug products are able to enter the market. For

example, the Hatch-Waxman Act only permits generic manufacturers to challenge patents listed for a new drug product one year before the expiration of the 5-year data protection period for the new drug product. During this same period, the Act exempts from patent infringement the actions taken by the generic manufacturer to prepare for and secure FDA approval of their generic versions of the new drug product. Permitting a generic manufacturer to start an early challenge to patents listed for the new drug while exempting those same companies for infringement of these listed patents creates an imbalanced system that is unfair to pharmaceutical innovators. That imbalance will create additional commercial uncertainty that the Act sought to eliminate, which, in turn, will reduce the incentives for pharmaceutical innovation.

3. So finally, Mr. Kushan, would you agree that promoting certainty between innovation and competition would see more treatments reach the marketplace?

Response: Yes, greater certainty will translate into more investments in pharmaceutical innovation and more pharmaceutical products actually reaching the market to address unmet medical needs.

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